

HEALTH SERVICES AND DEVELOPMENT AGENCY**MARCH 25, 2015****APPLICATION SUMMARY**

NAME OF PROJECT: Advanced Diagnostics Imaging d/b/a Southern Sports Medicine Institute

PROJECT NUMBER: CN1501-002

ADDRESS: 570 Hartsville Pike
Gallatin (Sumner County), TN 37066

LEGAL OWNER: Advanced Diagnostic Imaging
d/b/a Southern Sports Medicine Institute
570 Hartsville Pike
Gallatin (Sumner County), TN 37066

OPERATING ENTITY: NA

CONTACT PERSON: Byron Trauger, Esquire
(615) 256-8585
Trauger & Tuke
Nashville, TN 37219

DATE FILED: January 14, 2015

PROJECT COST: \$624,935.00

FINANCING: Cash Reserves

PURPOSE FOR FILING: Change of MRI equipment ownership and initiation of MRI services

DESCRIPTION:

Advanced Diagnostics Imaging PC, (ADI) a Tennessee professional private corporation formed in June 1972, is seeking approval in accordance with HSDA Staff Determination Letter No. 2014-SDL-011 to allow existing extremity magnetic resonance imaging (MRI) services approved in Thomas L. Gautsch, P.C., CN0110-088A, d/b/a Southern Sports Medicine Institute (SSMI), to continue to be provided at the same location under new ownership as ADI d/b/a Southern Sports Medicine Institute. Other than the change in ownership, there are no changes to the location or the extremity MRI equipment and services approved in CN0110-088A.

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This application has been placed under **CONSENT CALENDAR REVIEW** in accordance with TCA §68-11-1608(d) and Agency Rule 0720-10-.05

CRITERIA AND STANDARDS REVIEW

MAGNETIC RESONANCE IMAGING SERVICES

1. Utilization Standards for non-Specialty MRI Units.

a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.

The equipment is an existing GE Lunar X-Scan open MRI system approved in CN0110-088A. Designed exclusively for extremity MRI scans and used by patients of the private practice of Thomas L. Gautsch, M.D., the open MRI unit was acquired in 2004 following approval of the Certificate of Need.

Based on the MRI unit's limited clinical use as an existing Specialty MRI unit, this criterion does not apply to the project.

b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area

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are not adequate and/or that there are special circumstances that require these additional services.

e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

The criteria identified in items 1.b – 1.e above are not applicable to the applicant's proposed Specialty MRI service.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

Sumner County is the existing service area of the Specialty MRI service approved in Thomas L. Gautsch, CN0110-088A. Residents of the county accounted for approximately 568 or 79% of the total extremity MRI procedures of the practice in calendar year 2013. ADI expects no significant change to the service area as a result of its merger with SSMI.

It appears that this criterion has been met.

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

The project does not seek approval to add a new MRI unit. The existing extremity MRI unit approved in CN0110-088A will continue to be used by patients of the medical group practice.

It appears that the applicant will meet this criterion.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: $1.20 \text{ procedures per hour} \times \text{twelve hours per day} \times 5 \text{ days per week} \times 50 \text{ weeks per year} = 3,600 \text{ procedures per year}$

Mobile MRI Units: $\text{Twelve (12) procedures per day} \times \text{days per week in operation} \times 50 \text{ weeks per year}$. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

The subject of the application is an existing extremities MRI unit approved in Thomas Gautsch, P.C. CN0110-088A. The MRI service will continue under new ownership once Dr. Gautsch joins ADI.

This criterion does not apply to the project.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON, to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:

1. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound,

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- and MM unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
2. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;
 3. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

This criterion does not apply to the project.

- b. Dedicated fixed or mobile Extremity MR1 Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MR1 Unit shall provide documentation of the total capacity of the proposed MR1 Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MR1 procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.

The extremity MRI unit's schedule for patients of the practice is approximately 17 hours per week spread across two and a half days per week for an annual equivalent of 850 hours. At 1 hour per scan and an average of 733 scans per year from 2012 to 2014, the annual utilization of the existing averaged 86% of total capacity during the period (733 hours/850 hours).

Based on projected utilization of 726 and 730 scans in Year 1 and Year 2, it appears that the applicant will meet this criterion.

- c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.

This criterion does not apply to this application.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units.

This criterion does not apply to this application.

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

Documentation from the Food and Drug Administration, Department of Health and Human Services, was provided in the application confirming that the unit was registered and approved for use on or about 2/12/2002 in accordance with FDA certification requirements.

It appears that this criterion has been met.

- b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The project does not involve construction or related changes to the physical location of the existing MRI service. The applicant

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confirmed that the open bore extremity MRI unit acquired as a result of CN0110-088A was installed in a physical environment that conforms to federal manufacturer standards.

It appears that this criterion has been met.

- c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.

The applicant states that emergencies will continue to be managed by physicians of the practice and/or ACLS/BCLS certified medical office staff in accordance with accepted medical practice. The physician practice is located across the street from Sumner Regional Medical Center. Its physicians are members of the hospital's medical staff.

It appears that this criterion has been met.

- d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.

The applicant described the process pertaining to the method for obtaining prior approval for patient MRI services. The applicant will follow established protocol to ensure that MRI procedures are performed only when medically necessary.

It appears that this criterion has been met.

- e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

Per clarification provided in Item 7 of the 1/23/15 supplemental response, the applicant states that it meets the requirements set forth by a comparable entity and plans to maintain its current accreditation by the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL).

It appears that this criterion has been met.

- f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

As noted in the preceding item, the applicant states that it will maintain accreditation by the ICAMRL.

It appears that this criterion has been met.

- g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

As noted in the application, the extremity MRI service is a part of a physician group practice located across the street from Sumner Regional Medical Center. Dr. Gautsch has full admitting privileges at both hospitals in Sumner County and can admit patients of the practice at any time without the need for an emergency transfer agreement.

It appears that this criterion has been met.

8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant indicates data will continue to be submitted within the expected time frame.

It appears that this criterion has been met.

9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration; or

All or portions of Sumner County are located in Medically Underserved Areas designated by the Health Resources and Services Administration.

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The applicant meets this criterion.

- b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

The criterion does not apply to this application.

- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

The applicant states that the existing private practice participates in Medicare and one of the existing TennCare managed care organizations that operate in the service area (United Healthcare Community Plan). As a result of the merger between ADI and SSMI, participation will expand to all available TennCare MCOs, including United Healthcare Community Plan, Blue Care and TennCare Select.

It appears that the applicant meets this criterion.

- d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

It appears that this criterion does not apply to the project.

Staff Summary

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

The Certificate of Need is being sought as a result of arrangements for Dr. Gautsch to merge his private practice with the multi-specialty physician group practice Advanced Diagnostic Imaging (ADI) and allow existing extremity MRI services approved in CN0110-088A to continue to be provided in conjunction with Southern Sports Medicine Institute (SSMI). After joining the multi-specialty group, SSMI will be one of the individual care centers that constitute the private practice ADI. The MRI service will be limited to extremity scans in the same location in Gallatin (Sumner County), Tennessee, with no change in patient population or service area using the same open bore 0.2 Tesla MRI unit.

As a private physician practice, the proposed extremity MRI service of the applicant does not require licensure by the Tennessee Department of Health. As such, the applicant anticipates that services can be implemented within 30 days of approval of the application. The hours of operation will continue to include two 7 hour days per week from 9AM-4PM and one half day from 9AM to Noon for a total of approximately 17 hours per week.

Ownership

The applicant, Advanced Diagnostic Imaging, P.C., a Tennessee professional corporation formed in June 1972, will become the owner and operator of the extremity MRI services and will use the prior practice name as its d/b/a name (e.g. ADI Southern Sports Medicine Institute). Related highlights pertaining to the ownership of the applicant are as follows:

- 100% owned by licensed Tennessee physicians, consisting of radiologists, primary care, orthopedic and other multi-specialty physicians.
- No physician member has ownership interest of 5% or greater.
- No other ADI practice site presently provides MRI services.
- As clarified in Item 1 of the 1/23/15 supplemental response, some of the radiologist members who practice at ADI also have an indirect ownership in Middle Tennessee Imaging, LLC d/b/a Premier Radiology. However the two are legally separate organizations.
- An organizational chart with list of Premier Radiology sites was included in Supplemental 1.
- The applicant's plans to register and continue use of SSMI as an assumed name is consistent with recent acquisitions by ADI of other medical group practices. Review of Tennessee Secretary of State documentation about ADI revealed that ADI registered 6 "assumed names" in 2013 alone, including ADI d/b/a Advanced Health Partners, ADI d/b/a Pinnacle Surgical Partners and ADI d/b/a Nashville Neuroscience Group.

Facility and Extremity MRI Equipment Information

Key highlights of the applicant's extremity MRI service are noted below.

- Advanced Diagnostic Imaging will lease the building and extremity MRI equipment from Dr. Gautsch.
- The existing MRI service approved in CN0110-088A utilizes a 0.2 Tesla GE Lunar Scan MRI unit with Open Bore configuration. The applicant states that the MRI service has performed approximately 7,000 total MRI scans since its implementation in Fall 2004.
- The existing MRI service accounts for approximately 720 MRI scans per year or 7.2% of SSMI's annual 10,000 patient visit volumes.

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- The extremity MRI unit was manufactured in Italy in 2004. It was acquired by Dr. Gautsch's practice the same year at a total cost of approximately \$414,990.00 and has been fully paid for and depreciated.
- The MRI service utilizes approximately 369 square feet (SF) of dedicated space on the 1st floor of SSMI's existing freestanding 6,400 total SF building built in 1960.
- The service shares space with the practice for patient waiting, physical therapy and public rest rooms. Physician consultation takes place in 1 of 7 patient examination rooms or the PT treatment areas.
- Dr. Gautsch will continue to manage the operations and provide medical supervision for the extremity MRI service on a daily basis.
- ADI will bill for MRI procedures on a global basis inclusive of technical and professional (imaging interpretation) fees.
- After joining ADI, the images of the MRI service will be interpreted by board certified radiologists following secure and HIPAA compliant protocols.
- ADI will also bill for all other professional services performed by Dr. Gautsch.
- The site is within the city boundaries of Gallatin across the street from Sumner Regional Medical Center. It is also approximately 13 miles from the county's other hospital - Hendersonville Medical Center.
- No construction or renovation is necessary to modify the practice site containing SSMI's existing extremity MRI service

Project Need

The applicant states that the certificate of need for continuation of extremity MRI service approved in Thomas Gautsch, CN0110-088A, under new ownership by ADI is needed for the following reasons:

- To comply with HSDA Statute as identified by HSDA legal counsel in Staff Determination Letter No. 2014-SDL-011. As noted on pages 5 and 6 of the application, ADI must obtain a CON to replace CN0110-088A in order to perform or bill for MRI services under its change in ownership and merger with Dr. Gautsch.
- Continue access by residents of Sumner County to extremity, open MRI services at an established, busy private medical group practice specializing in orthopedic and sports medicine.
- Continue to provide access to specialized MRI service at an affordable, all inclusive "global fee" at significantly lower cost to patients and payors in comparison to charges of other MRI providers in Sumner County.
- Gain access to broader scope of patients through participation in ADI's larger range of health insurance contracts.
- Accommodate referrals of patients with orthopedic and sports injuries who may have special needs such as pediatric, obese and claustrophobic patients.

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Service Area Demographics

Advanced Diagnostic Imaging's extremity MRI service area will consist of Sumner County, the traditional primary service area of SSMI's practice. SSMI provided approximately 568 or 79% of 716 total MRI procedures to residents of Sumner County in 2013. Highlights of the applicant's proposed service area are provided as follows:

- The total population of Sumner County is estimated at 172,262 residents in calendar year (CY) 2014 increasing by approximately 5.8% to 183,406 residents in CY 2018.
- The overall Tennessee statewide population is projected to grow by 3.7% from 2014 to 2018.
- Residents age 65 and older account for approximately 14.6% of the total county population compared to 16% statewide.
- The age 65 and older resident population is expected to increase by 6.1% compared to 6.1% statewide from CY2014 - CY2018.
- The median age in Sumner County is 38.7 compared to age 38 statewide.
- The number of residents enrolled in TennCare is approximately 14% of the total county population compared to 18.1% statewide.

Historical and Projected Utilization

Other than the change of ownership to Advanced Diagnostics Imaging, the applicant expects no significant change in the extremity MRI service approved in Thomas Gautsch, CN01101-088A. Projected utilization will be consistent with the historical volumes of Southern Sports Medicine Institute (SSMI) representing approximately 7% of SSMI's total annual patient visits. Residents of Sumner County will continue to account for the majority of scans by patients of SSMI. Additional key factors that apply to the projected utilization of the MRI service are as follows:

- No changes in practice site, equipment or service area.
- The primary clinical applications will remain scans of the upper and lower extremities.
- Participation in a larger range of health insurance contracts,
- Continuity of care through Dr. Gautsch's continued participation and clinical leadership in all aspects of SSMI's operations.

The historical and projected MRI utilization is shown in the table below.

Table 1- Applicant's Historical and Projected Utilization

2011	2012	2013	% Change '11-'13	Year 1	Year 2
636	720	723	13.7%	726	730

Sources: HSDA Equipment Registry, Projected Data Chart, CN1501-002

The inventory and 3 year utilization trend of existing Sumner County MRI providers and their use by residents of the county was identified on page 20 of the application. On average, Sumner residents accounted for approximately 79% of total annual provider volumes during the period.

A snapshot of provider MRI utilization trends and use by residents of the PSA in CY 2013 is shown in the tables below. Utilization for each provider is noted in the second table on page 20 of the application.

Table 2 - Historical Utilization of MRI Providers in Sumner County

#Providers	Current # units (type)	2011	2012	2013	% Change '11-'13	Sumner County Resident Procedures (2013)
6	5 fixed; 1 mobile	9,278	9,621	10,100	8.9%	7,996

Table 3 - Sumner County Resident MRI Utilization, 2011-2013

	2011	2012	2013
Resident Procedures at Sumner County Provider Sites	7,338	7,548	7,996
Resident Procedures at all TN Provider Sites	15,411	15,167	14,592
Use of Sumner County providers as a % of Total Resident Procedures	47.6%	49.8%	54.8%
Total Resident MRI Procedure Rate per 1,000 population	89.2 per 1,000	91.1 per 1,000	91 per 1,000

HSDA Equipment Registry, TDH population estimates

The tables reflect the following:

- Tables 1 and 2 - SSMI's utilization increased by approximately 13.7% from 2011 - 2013 compared to 8.9% for all MRI providers in the county during the period.
- Table 2 - approximately 79% of MRI provider procedures were performed for Sumner County residents in 2013. MRI use of existing providers in the county appears to be increasing as measured by a 8.97% increase in utilization from CY 2011 - CY2013.

- Table 3 – Overall it appears that there is a significant amount of outmigration by residents of Sumner County to providers located in other counties of Tennessee although resident use of Sumner County providers appears to be increasing.

Project Cost

The total project cost \$624,935.00. Major costs are as follows:

- The facility cost is \$41,935 or 6.7% and was determined using the estimated fair market value of the 369 square foot office space dedicated to the practice's extremity MRI service. Since it is higher than the actual 5-year facility lease cost of \$22,140, it is used in the Project Cost Chart in accordance with Agency Rules.
- The equipment cost is \$500,000 or 80% of the total project cost. This amount is the estimated fair market value (FMV) of the existing MRI extremity 0.2 Tesla open MRI unit.
- Per Item 10 of the 1/23/15 supplemental response, the MRI equipment amount is based on the purchase of a replacement unit at today's prices. The estimate includes savings based on paying directly for repairs when necessary in lieu of purchasing a service contract from the vendor. Additional savings include the reuse of ancillary equipment such as the digital film printer and modular screened pavilion.
- The FMV of extremity MRI unit is lower than both the actual re-sale or residual value of the 11 year old unit (approximately \$100,000) and the equipment lease cost documented in the application (\$30,000). The equipment FMV is used for CON purposes in accordance with HSDA Rules.
- For other details on revised project cost of the project, see the Project Cost Chart on page 22 of the application.

Projected Data Chart

The Projected Data Chart on page 26 of the application reflects \$1,529,334 in total gross operating revenue on 726 procedures in Year 1 (average of \$2,107 per MRI procedure). The Projected Data Chart reflects the following:

- Gross operating revenue increases by less than 1% from Year 1 to \$1,537,760 on 730 procedures in Year 2.
- Net operating income (NOI) averages approximately \$229,250.00 per year in Year 1 and Year 2 or approximately 15% of gross operating revenue.
- The applicant allocates \$4,000 per year for charity and \$61,250/year for bad debt. *Note: as indicated on page 29-R, SSMI participates as a specialist in the Salvus Center, established by physicians, community leaders and others to provide coordinated and comprehensive care for the medically indigent of Sumner County. Approximately 4 charity cases were referred by the Salvus Center to SSMI in 2014.*

- Contractual adjustments account for the highest deductions from revenue averaging approximately 66.5% of gross revenue per year. It appears that the applicant's 29% combined Medicare/TennCare payor mix may help explain why contractual adjustments are higher for this service.

Charges

Advanced Diagnostic Imaging's established fee schedule will replace SSMI's fee schedule when Dr. Gautsch joins ADI. For extremity MRI, the projected average gross charge will increase from \$1,570 per scan, exclusive of professional fees, to approximately \$2,107 per scan based on a global fee basis (both technical and professional fees are included). Highlights of the applicant's charges are as follows:

- The fee schedule of the applicant's global MRI charges with breakout by CPT classification compared to other existing MRI providers is shown on page 28 of the application.
- The average gross charge for MRI is \$2,107/scan. After deductions, the projected average net charge is \$1,480/scan.
- Average gross charge is lower than other outpatient imaging providers in Sumner County and significantly less than the \$4,469/scan average gross charge of hospital based providers in CY2013.
- According to HSDA records, the \$2,107 average gross charge is below the median MRI charge of \$2,175/scan and the 3rd quartile charge of \$3,498.94/scan for the CY 2011 - CY2013 period.

Payor Mix

- SSMI currently participates in United Healthcare Community Plan.
- Participation will increase to all active TennCare MCOs in Sumner County when SSMI joins Advanced Diagnostics Imaging, including United HealthCare Community Plan (formerly AmeriChoice), TennCare Select, Blue Care and AmeriGroup.
- As part of ADI, the 37 radiologists employed by ADI will provide professional image interpretation services for the extremity MRI service. The applicant states that all ADI radiologists are contracted in-network with TennCare MCO plans in the service area.
- The revised projected gross operating revenue by payor source is shown in the table below.

MRI Payor Source, Year 1

Payor Source	Gross Revenue	As a % of Total
Medicare	\$270,692	17.7%
TennCare	\$177,403	11.6%
Managed Care	\$157,521	10.3%
Commercial	\$880,896	57.6%
Self-Pay	\$,7647	0.5%
Other	\$35,175	2.3%
Total	\$1,529,334	100%

Financing

Funding support for the project will be provided from cash reserves of Advanced Diagnostics Imaging.

- As noted, ADI will negotiate operating leases with Dr. Gautsch for use of the office space and the MRI equipment.
- A 1/20/15 letter from Mark Gaw, CFO, was provided in Supplemental 1 that attests to ADI's ability to financially support the project from cash-on-hand amounts.
- Review of the Balance Sheet for ADI revealed total current assets of \$2,039,865, including operating cash of \$1,952,131 and total current liabilities of \$380,502 for the period ending October 31, 2014. As a result, ADI's Current Ratio was approximately 5.35 to 1.0 for the period.

Note to Agency Members: current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

Other than the change to professional image interpretation by ADI radiologists, no significant changes in direct clinical or administrative support staff is anticipated for the existing extremity MRI service.

- Time allocated to the MRI service for a staff radiology technician amounts to less than a single fulltime equivalent position.
- A small percentage of other staff activity for nursing, reception and billing staff in an amount averaging approximately 720 hours per year is also allocated to the service.

Licensure/Accreditation

As a private medical group practice, the applicant is not licensed by Tennessee Department of Health. Advanced Diagnostics Imaging d/b/a SSMI is pending renewal of its accreditation by the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories which expired on December 31, 2014.

Corporate documentation, site control information and a vendor MRI equipment quote documenting the purchase price of the extremity MRI unit identified in Thomas Gautsch, CN0110-088A, are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, denied, or pending applications for this applicant.

Outstanding Certificates of Need:

Southern Sports Medicine Surgery Center, CN1204-019A, has an outstanding Certificate of Need that expired on November 1, 2014. Although this project has been completed, it remains in Outstanding CON status pending receipt of a Final Project Report. The project was approved at the September 26, 2012 Agency meeting for the relocation of the single specialty ASTC approved in CN1104-013AVS from 1163 Nashville Pike, Gallatin (Sumner County), TN to 127 Saundersville Pike, Suite A, Hendersonville, (Sumner County), Tennessee. The project includes the expansion from single specialty to multi-specialty services. The project cost is **\$3,355,533.00**. *Project Status Update: the project was actually completed and licensed by TDH effective August 18, 2014, approximately 3 months before the CON expiration date. HSDA staff has been in contact with the applicant to request a Final Project Report for the project and was advised by e-mail on 2/26/15 that an FPR was being prepared and would be submitted as soon as possible.*

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no Letters of Intent or denied or pending applications or outstanding Certificates of Need for similar service area entities proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG; 02/24/15

LETTER OF INTENT



State of Tennessee
Health Services and Development Agency

Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, TN 37243

www.tn.gov/hstda Phone: 615-741-2364 Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the TENNESSEAN _____ which is a newspaper
 of general circulation in SUMNER _____, Tennessee, on or before 1/09, 2015
(Name of Newspaper)
County (Month / day)(Year)
 for one day.

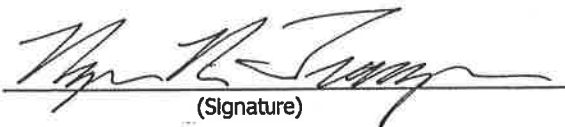
This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Advanced Diagnostic Imaging, P.C., a professional private practice owned by itself, with an ownership type of Professional Corporation, and managed by itself, intends to file an application for a Certificate of Need to allow existing MRI services granted to Thomas L. Gautsch M.D., P.C. in the office of and in conjunction with the practice of Southern Sports Medicine Institute to continue to be provided in the same location, under ADI, d/b/a Advanced Health Partners, the multi-specialty physician group private practice that Dr. Gautsch is joining. No new equipment or construction will be required. The same open, extremity scanner and location, 570 Hartsville Pike, Gallatin TN, will be used and remain in place. The total anticipated project cost is \$624,935, inclusive of the value of the occupied space, legal/consulting fees associated with this application, and potential future cost of replacement of the existing MRI unit.

The anticipated date of filing the application is on or before January 14, 2015.

The contact person for this project is

Byron R Trauger, Attorney,
 who may be reached at Trauger and Tuke,
 222 Fourth Avenue North, Nashville, TN 37219. (615) 256-8585


 (Signature)

1/09/2015
 (date)

btrauger@tnlaw.net, tgautsch@kneeguru.com
 (E-mail Addresses)

ORIGINAL APPLICATION

1. **Name of Facility, Agency, or Institution**

Advanced Diagnostic Imaging, P.C. d/b/a
Southern Sports Medicine Institute
Name
570 Hartsville Pike
Street or Route
Gallatin
City
TN
State
Sumner
County
37066
Zip Code

2. **Contact Person Available for Responses to Questions**

Byron R Trauger
Name
Trauger and Tuke
Company Name
222 Fourth Avenue North
Street or Route
Nashville
City
Attorney
Association with Owner
Esq.
Title
btrauger@tntlaw.net
Email address
TN
State
37219
Zip Code
(615) 256-8585
Phone Number
615-256-7444
Fax Number

3. **Owner of the Facility, Agency or Institution**

Advanced Diagnostic Imaging, P.C. d/b/a Advanced Health Partners
d/b/a Southern Sports Medicine Institute
Name
570 Hartsville Pike
Street or Route
Gallatin
City
TN
State
615-452-3320
Phone Number
Sumner
County
37066
Zip Code

4. **Type of Ownership of Control (Check One)**

- | | | | |
|---------------------------------|-----------|-------------------------------|-------|
| A. Sole Proprietorship | _____ | F. Government (State of TN or | _____ |
| B. Partnership | _____ | Political Subdivision) | _____ |
| C. Limited Partnership | _____ | G. Joint Venture | _____ |
| D. Corporation (For Profit) | <u>XX</u> | H. Limited Liability Company | _____ |
| E. Corporation (Not-for-Profit) | _____ | I. Other (Specify) | _____ |

3. Owner of the Facility, Agency or Institution

Response: The applicant, Advanced Diagnostic Imaging, P.C. ("ADI") is a Tennessee professional corporation that employs many physicians around the Middle Tennessee area; it is regarded as a "group practice" under Stark regulations. Advanced Health Partners is a registered assumed name that ADI uses to refer to its medical practice as a whole at all locations, and therefore also listed in the published LOI. When physicians join ADI, they practice at their practice location where they historically have practiced and typically use their prior practice name as a d/b/a. This CON application anticipates Dr. Gautsch joining the Southern Sports Medicine Institute to ADI, with the desire to continue already approved and existing MRI services at that practice location. When Dr. Gautsch joins ADI, he will continue to practice at his Gallatin location, and as part of ADI will use Southern Sports Medicine Institute as a d/b/a of ADI when referring to his practice location. Once joined, and with approval of this CON application, the name "Southern Sports Medicine Institute" will be registered with the TN Secretary of State as an additional assumed name of ADI, the new CON owner, pursuant to the provisions the Tennessee Business Corporation Act, and with the consent and release by Dr. Gautsch, the current registered agent/user.

4. Type of Ownership Control

Response: Advanced Diagnostic Imaging, P.C. is a Tennessee professional corporation. It is 100% owned by TN licensed physicians, none of whom own a 5% or greater ownership interest. No healthcare institutions own an ownership interest in Advanced Diagnostic Imaging.

5. **Name of Management/Operating Entity (If Applicable)**

N/A

Name _____

Street or Route _____

County _____

City _____

State _____

Zip Code _____

**PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

6. **Legal Interest in the Site of the Institution (Check One)**

- | | |
|--------------------------------------|--------------------------|
| A. Ownership _____ | D. Option to Lease _____ |
| B. Option to Purchase _____ | E. Other (Specify) _____ |
| C. Lease of <u>5</u> Years <u>XX</u> | |

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

7. **Type of Institution (Check as appropriate--more than one response may apply)**

- | | |
|---|---|
| A. Hospital (Specify) _____ | I. Nursing Home _____ |
| B. Ambulatory Surgical Treatment
Center (ASTC), Multi-Specialty _____ | J. Outpatient Diagnostic Center _____ |
| C. ASTC, Single Specialty _____ | K. Recuperation Center _____ |
| D. Home Health Agency _____ | L. Rehabilitation Facility _____ |
| E. Hospice _____ | M. Residential Hospice _____ |
| F. Mental Health Hospital _____ | N. Non-Residential Methadone
Facility _____ |
| G. Mental Health Residential
Treatment Facility _____ | O. Birthing Center _____ |
| H. Mental Retardation Institutional
Habilitation Facility (ICF/MR) _____ | P. Other Outpatient Facility
(Specify) _____ |
| | Q. Other (Specify) <u>Physician group</u> <u>XX</u> |

8. **Purpose of Review (Check) as appropriate--more than one response may apply)**

- | | |
|--|--|
| A. New Institution _____ | G. Change in Bed Complement
[Please note the type of change
by underlining the appropriate
response: Increase, Decrease,
Designation, Distribution,
Conversion, Relocation] |
| B. Replacement/Existing Facility _____ | |
| C. Modification/Existing Facility _____ | |
| D. Initiation of Health Care
Service as defined in TCA §
68-11-1607(4)
(Specify) <u>MRI</u> <u>XX</u> | H. Change of Location _____ |
| E. Discontinuance of OB Services _____ | I. Other (Specify) _____ <u>XX</u> |
| F. Acquisition of Equipment _____ | <u>Continue existing</u> |

9. Bed Complement Data*Please indicate current and proposed distribution and certification of facility beds.*

		<u>Current Beds Licensed</u>	<u>*CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	<div>N/A</div>	_____	_____	_____	_____	_____
B. Surgical		_____	_____	_____	_____	_____
C. Long-Term Care Hospital		_____	_____	_____	_____	_____
D. Obstetrical		_____	_____	_____	_____	_____
E. ICU/CCU		_____	_____	_____	_____	_____
F. Neonatal		_____	_____	_____	_____	_____
G. Pediatric		_____	_____	_____	_____	_____
H. Adult Psychiatric		_____	_____	_____	_____	_____
I. Geriatric Psychiatric		_____	_____	_____	_____	_____
J. Child/Adolescent Psychiatric		_____	_____	_____	_____	_____
K. Rehabilitation		_____	_____	_____	_____	_____
L. Nursing Facility (non-Medicaid Certified)		_____	_____	_____	_____	_____
M. Nursing Facility Level 1 (Medicaid only)		_____	_____	_____	_____	_____
N. Nursing Facility Level 2 (Medicare only)		_____	_____	_____	_____	_____
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)		_____	_____	_____	_____	_____
P. ICF/MR		_____	_____	_____	_____	_____
Q. Adult Chemical Dependency		_____	_____	_____	_____	_____
R. Child and Adolescent Chemical Dependency		_____	_____	_____	_____	_____
S. Swing Beds		_____	_____	_____	_____	_____
T. Mental Health Residential Treatment		_____	_____	_____	_____	_____
U. Residential Hospice		_____	_____	_____	_____	_____
TOTAL		_____	_____	_____	_____	_____

*CON-Beds approved but not yet in service

10. Medicare Provider Number 3372986 (ADI)
 Certification Type Private Physician's Group Practice

11. Medicaid Provider Number 3372986 (ADI)
 Certification Type Private Physician's Group Practice

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid?

N/A

13. *Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? YES If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.*

Response: Currently, Southern Sports Medicine Institute contracts with United Healthcare Community Plan (Americhoice). ADI contracts/participates in all TennCare MCOs operational in the service area as of January 1, 2015, on an in-network basis. These include Amerigroup, United Healthcare Community Plan (Americhoice), TennCare Select, and BlueCare. With the granting of this CON, and the joining of SSMI to ADI, SSMI too will be in-network in these additional TennCare MCOs under ADI's existing contracts, and enrollees will gain expanded in-network access to these MRI services. With the granting of this CON application, the 37 radiologists employed by ADI will now read the MRI images. As employees of ADI, they also are all in-network with all of these MCOs.

SECTION B: PROJECT DESCRIPTION

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Response:

Patients who seek care at Southern Sports Medicine Institute, virtually always come to see us because they are in pain and/or have limited mobility and function due to new or chronic joint injury. SSMI specializes in the care of orthopedic and sports injuries. Often the use of MRI technology greatly facilitates the determination of a diagnosis and formulation of a treatment plan for the patients we see.

In 2001, CON #CN0110 – 088A was granted to Thomas L. Gautsch, M.D., PC "...in the office of, and in conjunction with the practice of Southern Sports Medicine Institute . . . Limited to orthopedic extremity MRI" to obtain the first office based, open scanner of its kind in Middle Tennessee. Since then, we have been able to offer our patients the benefits, ease and convenience of medically necessary MRI scans in a fully open scanner, right in our office, often on the same day as their initial visit with our Doctors.

Now, in concert with evolving changes in healthcare, Southern Sports Medicine Institute is formally joining with other physicians as part of the multi-specialty physician group Advanced Health Partners. Outwardly, neither the d/b/a name SSMI nor the practice will change significantly. Southern Sports Medicine patients will continue to be seen and treated in the same way, in the same office. They will continue to have their Doctor visits, X-rays, Physical Therapy, and MRI scans here as they always have. However, joining SSMI into AHP (ADI) and its larger range of contracts will allow a broader scope of patients within our service area to be seen at Southern Sports Medicine Institute within their insurer's network. With this action, patients in new exchange plans, additional commercial plans, and additional TennCare MCOs contracted with AHP/ADI will now be able to access SSMI (and this scanner) within their network.

We will continue doing business as Southern Sports Medicine Institute. Advanced Health Partners, the ADI physician group practice, will become the billing provider for all of our services.

This new "orthopedic extremity MRI" CON application is being made after seeking the opinion of HSDA's General Counsel as to whether the existing MRI CON would suffice for MRI services to continue after the joining of SSMI into AHP/ADI. Based on his opinion, we seek HSDA approval with this new CON application in ADI's name to replace the original. While the Physician practice and its in-office MRI scanner and services won't change, the named contracting and billing entity

will. Since this existing MRI scanner's CON was issued to a "professional practice" rather than a "healthcare institution", and therefore not issued a license for the MRI separate from the CON, current TN rules require a new CON in the name of Advanced Diagnostic Imaging, PC d/b/a Advanced Healthcare Partners, for SSMI to continue to provide these existing MRI scanning services after Dr. Gautsch (SSMI) joins them.

The project already is operating well, with stable staffing, covering all of its expenses, and has paid off all its debt. The existing scanner is in excellent condition, well maintained, the first independently certified scanner in Sumner County (The Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories -- ICAMRL), and is expected to continue to function for years to come. It is also the only open scanner in Sumner County and is tremendously convenient for patients.

At the time of the original CON's granting, there were two physicians in the SSMI practice, including Dr. Gautsch. Plans to add additional providers over time, who would also utilize the MRI services, were explicitly described in that approved application. In the ensuing 14 years, 8 additional physician or non-physician providers have, at various times, worked with the group and utilized this scanner. As of this application, besides Dr. Gautsch there is one additional AHP physician provider, also an Orthopedic Surgeon and one non-physician provider who works with him, expected to order extremity MRI scans with this scanner. There are plans to add at least one additional provider to the SSMI practice to replace one who has recently moved. There are currently no other AHP/ADI physician practices based in Sumner County.

SSMI MRI scans have always been read by board certified Radiologists specializing in musculoskeletal MRI, utilizing the latest in secure, HIPAA compliant, industry-standard tele-radiology. AHP/ADI employs a number of board certified radiologists who will now read the studies utilizing similar methods -- as they do for a number of other scanning facilities around Tennessee.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

Response: The project involves none of the above.

Dr. Gautsch's practice, Southern Sports Medicine Institute is coming into the physician

practices of ADI who will now be the named provider of the services including the MRI scans. Of necessity, this application seeks a new CON to name ADI as the entity who will now contract and bill for the MRI services as provided, in conjunction with this practice, utilizing this same open bore 0.2 Tesla GE Lunar E-Scan MRI, at this same location, serving the same patient population from the same service area. No construction, modification, relocation or renovation of the facility is sought.

The scanner and its support equipment currently occupy approximately 308 ft.² in the offices of Southern Sports Medicine Institute in Gallatin. Additionally, 7.2% utilization of the office's approximately 850 ft.² of waiting area and bathrooms, or 61 ft.² are attributed to the scanner's patients on the basis of (720 annual scans)/(10,000 total office visits) at the location.

This MRI scanner is an integral part of the physician practice. SSMI occupies the entirety of a an approximately 6,400 ft.², commercially zoned, freestanding brick doctor's office building, originally built in about 1960, and subsequently remodeled several times. All clinical space, including the MRI scanner, is located on the ground level. Patients of the practice, often undergo MRI scanning as an integral part of their visit, which may also include plain radiographs in the X-Ray room, physician consultation before and/or after scanning in one of the 7 patient examination rooms, or physical therapy in the PT treatment areas. The MRI scanner is installed with its equipment in a dedicated space that exceeds manufacturer specifications, as illustrated in the attached floor plans and manufacturer's installation illustration. The practice's waiting room, 5 bathrooms, private examination rooms and physician office are all available to meet the needs of patients, including those who may also be undergoing MRI scanning that day, as well as the physician(s) and staff attending them.

Studies will continue to all be read by Board Certified radiologists. The hours of scan scheduling have typically been on the hour, 9AM to 4 PM, two days, and 9AM to 12noon one day per week. Other days or extended evening and/or weekend hours have occasionally been made available as physician and patient needs have required.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Response: N/A

C. *As the applicant, describe your need to provide the following health care services (if applicable to this application):*

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

Response: These existing MRI scanner services have proven to be a great convenience for the patients of this group, some of whom seek these specific physicians from a significant distance, and who are very often able to have MRI scanning as part of the same office visit and work-up.

D. *Describe the need to change location or replace an existing facility.*

Response: N/A. There is no need to change location nor replace the existing facility (or services).

E. *Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:*

1. For fixed-site major medical equipment (not replacing existing equipment):

a. Describe the new equipment, including:

1. Total cost ;(As defined by Agency Rule).
2. Expected useful life;
3. List of clinical applications to be provided; and
4. Documentation of FDA approval.

Response:

1. No new or major medical equipment will be acquired. Dr. Thomas Gautsch will continue to own the scanner, whose original cost was less than \$500,000 new and has already been fully paid off and depreciated. He will lease it and the space it occupies to his group. Please see attached executed lease between ADI and Dr. Gautsch, and the original purchase agreement documenting his ownership as an attachment under C, Economic Feasibility Item 8. The current estimated Fair Market Value of the

equipment is: \$100,000

This GE Lunar E-Scan MRI was built in 2004 by Esaote in Italy utilizing a precision permanent magnet and standard, replaceable/upgradeable PC computer equipment with a Microsoft Windows based software platform. Unlike superconducting magnets, with proprietary computer workstations, this scanner has less complex systems and fewer parts to wear out or replace. Most of the components and electronics are modular and can be, and occasionally have been replaced as necessary, including coils and a replacement RF unit, with software upgrades installed as available.

The scanner's original cost was well below the threshold definition of "Major Medical Equipment", currently set at \$2,000,000, with the attendant more stringent requirements. When replacement is indicated, new units of similar function are even less expensive now and still would not represent the acquisition or replacement of "Major Medical Equipment" per TCA 68-11-1607(a)(6).

Although this application merely seeks to continue existing MRI services with the same existing scanner, location, staff and set-up, for the purposes of calculating this application's Total Project Costs, an allowance of \$500,000 is accounted, although it may not actually be required for a number of years, nor likely cost that much. An additional future Projected Data year "***", reflecting a year when the scanner has been replaced, is provided following Section C, Item 4, Projected Data Chart.

This scanner has been maintained by the same technicians from the time of its installation, originally under a service contract and subsequently for regular maintenance and as-needed for repair. Over the previous several years that has averaged \$2,664 per year, which is included in the Project Data Chart D 9 Other Expenses. ADI also plans to maintain the equipment similarly, as it does typically for all of its equipment, paying for repairs and regular servicing when and as needed.

2. As a practice based specialty unit, this particular MRI has been well cared for and relatively gently used, with still fewer than 7000 total scans since its installation in 2004. Every indication is that the scanner will continue to function well for many years to come. All regularly performed tests remain well within normal operating parameters.

3. The primary CPT codes ordered for this unit have been:

- 73221 MRI upper extremity, any joint w/o contrast
- 73721 MRI lower extremity, any joint w/o contrast

Other codes which occasionally may be used include:

- 73218 MRI upper extremity, other than joint w/o contrast
- 73220 MRI upper extremity, other than joint with and w/o contrast
- 73223 MRI upper extremity, any joint with and w/o contrast
- 73718 MRI lower extremity, other than joint w/o contrast
- 73720 MRI lower extremity, other than joint with and w/o contrast
- 73723 MRI lower extremity, any joint with and w/o contrast

MRI scans are both reviewed by Board Certified Orthopedic surgeons with many years of experience interpreting these scans, and also formally read by Board Certified Musculoskeletal Radiologists. Images are immediately sent via HIPAA compliant industry standard secure protocols directly from the unit to the Radiologist for

interpretation. The reports are then made available to the referring physician via secure login to their hosting site. After joining ADI, scans will be read by Board Certified Radiologists of ADI following similar secure and HIPAA compliant protocols.

4. Please see below results of FDA Medical Devices database query documenting FDA approval.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K020164>

The screenshot shows the FDA's 510(k) Premarket Notification database query results for device K020164. The page header includes the FDA logo and navigation links. The main content area displays the following information:

New Search		Back To Search Results
Device Classification Name	System, Nuclear Magnetic Resonance Imaging	
510(k) Number	K020164	
Device Name	E-SCAN XQ	
Original Applicant	BIOSOUND ESAOTE, INC. 8000 Castaway Dr. Indianapolis, IN 46250	
Original Contact	Colleen Densmore	
Regulation Number	882.1000	
Classification Product Code	LNU	
Date Received	01/17/2002	
Decision Date	02/12/2002	
Decision	Substantially Equivalent (SESE)	
Regulation Medical Specialty	Radiology	
510(k) Review Panel	Radiology	
Summary	Summary	
Type	Special	
Reviewed By Third Party	No	
Combination Product	No	

Page Last Updated: 12/15/2014
Note: If you need help accessing information in different file formats, see instructions for Downloading Viewers and Players.

b. Provide current and proposed schedules of operations.

Response: The hours of scan scheduling have typically been on the hour, between 9AM to 4 PM, two days, and 9AM to 12 noon one day per week (17 hours/week). Other days or extended evening and/or weekend hours have occasionally been made available as physician and patient needs have required, particularly during Football Season. This is not expected to change.

2. For mobile major medical equipment:

- List all sites that will be served;
- Provide current and/or proposed schedule of operations;
- Provide the lease or contract cost.
- Provide the fair market value of the equipment; and
- List the owner for the equipment.

Response: N/A

3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Response: The Scanner and its space will be leased. See attached executed lease.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. Size of site (in acres);
2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Response: See the attached plot plan.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Response: Gallatin does not have public transportation. The office is located in an established and fully developed area, on one of the main thoroughfares in Gallatin, at ground level, with immediately adjacent parking, near a number of other medical offices and the local Hospital

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: DO NOT SUBMIT BLUEPRINTS. Simple line drawings should be submitted and need not be drawn to scale.

Response: See the attached floor plans.

V. For a Home Health Agency or Hospice, identify:

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

Response: N/A

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be

granted unless the action proposed in the application for such Certificate is necessary to

provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

Magnetic Resonance Imaging (Updated Standards and Criteria)

1. Utilization Standards for non-Specialty MRI Units.

- a. An applicant proposing a new non-Specialty stationary MRI unit should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2800 procedures per year by the third year of service and for every year thereafter.

Response: Does not apply. This is an existing Specialty MRI.

- b. Providers proposing a new non-Specialty mobile MRI unit should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

Response: Does not apply. This is an existing Specialty MRI.

- c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

Response: Does not apply. This is an existing Specialty MRI.

- d. Mobile MRI units shall not be subject to the need standard in paragraph 1b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's geographical area are not adequate and/or that there are special circumstances that require these additional services.

Response: Does not apply. This is an existing Specialty MRI.

2. **Access to MRI Units.** All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

Response: Does not apply. This is an existing Specialty MRI. However, this location is accessible by all of the service area's population.

3. **Economic Efficiencies.** All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: Does not apply. This is an existing Specialty MRI. As such however, it represents one of the more cost efficient MRI technologies with its capabilities. It also is the only open scanner in Sumner County, and its availability to patients within the practice where they are already being cared for, provides the highest possible level of direct access to MRI scanning for our patients, as well as the highest degree of care continuity for them.

4. **Need Standard for non-Specialty MRI Units.**

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: $1.20 \text{ procedures per hour} \times \text{twelve hours per day} \times 6 \text{ days per week} \times 50 \text{ weeks per year} = 3,600 \text{ procedures per year}$

Response: Does not apply. This is an existing Specialty MRI.

Mobile MRI Units: $\text{Twelve (12) procedures per day} \times \text{days per week in operation} \times 50 \text{ weeks per year}$. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

Response: Does not apply. This is a fixed, existing Specialty MRI.

5. **Need Standards for Specialty MRI Units.**

- a. **Dedicated fixed or mobile Breast MRI Unit.** An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:

1. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;

2. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit is in compliance with the federal Mammography Quality Standards Act;
3. It is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.
4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

Response: Does not apply. This is an existing Extremity MRI.

- b. Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity.

Response: This existing, fixed Extremity MRI Unit is typically available for a total of 17 hours per week, divided into two and a half days per week. It operates fifty weeks out of the year, for a total of 850 operating hours per year. A typical scan, including patient interview, preparation, positioning, scanning and debriefing, takes approximately 1 hour, thus scans are scheduled at one-hour intervals. At 720 scans per year, the scanner is already performing at approximately 85% capacity, by these criteria.

- c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity.

Response: Does not apply. This is an existing fixed Extremity MRI.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.

Response: Separate inventories are accounted, and the CON will continue to include these limitations.

7. ***Patient Safety and Quality of Care.** The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.*

- a. *The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.*

Response: The scanner is FDA approved. Please see above response and documentation with E.1.a.4.

- b. *The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.*

Response: This existing scanner was installed in a physical environment that conforms to applicable federal standards, and manufacturer's specifications. As part of a private medical group practice, Tennessee does not license it apart from the professional licensing. Please also see attached Manufacturer's installation guide under section B.II.A, This installation exceeds those requirements.

- c. *The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.*

Response: This MRI is already an integral part of this physician medical office and practice. After the merger into ADI, emergencies will still be managed by the physicians, and/or ACLS/BCLS certified medical office staff, in conformity with accepted medical practices until Paramedics arrive to transport patients across the street to the Emergency Room or direct admission to the hospital.

- d. *The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.*

Response: All current MRI scans and procedures are performed only by physician order, certified as medically necessary, subjected to utilization review, independent certification, and reviewed by reading Radiologists and the Radiologist Medical Director to ensure the medical appropriateness of the referral and to insure against inappropriate duplication of prior studies. This will continue under the new CON.

- e. *An applicant proposing to acquire any MRI Unit, including Dedicated Breast and Extremity MRI Units, shall demonstrate that:*
- f. *All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.*

Response: All standards and protocols currently in place, are according to a board certified Radiologists instruction and supervision and meet the standards necessary to have obtained its current independent ICAMRL certification. All scans are and will be interpreted by a board certified Radiologist.

- g. *All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.*

Response: This scanner is an integral part of a physician group practice located directly across the street from the Hospital, not a separate freestanding scanning facility. Dr. Gautsch maintains admitting privileges at both Sumner County Hospitals and can admit any patients to either hospital directly from the office into the hospital, at any time, without need of other agreements or arrangements.

8. *The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.*

Response: The applicant will continue to provide the Tennessee Health Services and Development Agency requested data in a timely fashion.

9. *In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care." the HSDA may decide to give special consideration to an applicant:*

- a. *Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;*
- b. *Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or*
- c. *Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.*

Response: The existing MRI services are already contracted with Medicare and one TennCare MCO, which will expand immediately to Medicare and all TennCare MCOs operating in Sumner County upon SSMI's joining AHP/ADI, with whom their contracts are already in place.

2. *Describe the relationship of this project to the applicant facility's long-range development plans, if any.*

Response: The applicant is not a healthcare facility, and therefore has no long-range facility development plans. However, as physicians our desire is to provide the best, most cost-effective and convenient care for our patients. Coming together as a group allows us to help our patients, not only to take advantage of the benefits of coordinating their care between physicians, but also allows us a voice in the ongoing development of different models of care for our patients.

3. *Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. **Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).***

Response: See attached map. Southern Sports Medicine Institute's principle service area for its existing MRI services is Sumner County. Patients are also occasionally seen from other nearby counties as well. That is not expected to change.

**MRI Provider Utilization by Residents of Sumner County
from Medical Equipment Registry**

	2011	2012	2013	Percent Changed from 2011 to 2013
Patient Procedures at Southern Sports Medicine Institute (All Residents)	636	720	716	12.58%
Patient Procedures at all Other Sumner County Providers (All Residents)	8642	8901	9384	8.59%
Total of Sumner County Provider Patient Procedures (All Residents)	9278	9621	10100	8.86%
Patient Procedures at Southern Sports Medicine Institute (Sumner County Residents Only)	516	568	568	10.08%
Patient Procedures at all Other Sumner County Providers (Sumner County Residents Only)	6822	6980	7428	8.88%
Total of Sumner County Provider Patient Procedures (Sumner County Residents Only)	7338	7548	7996	8.97%
Percent of Sumner County Residents Utilizing Sumner County Providers for MRI Procedures	79.09%	78.45%	79.17%	

Medical Equipment Registry - 12/22/2014

4. A. Describe the demographics of the population to be served by this proposal.

Response: Please see summary table below.

Sumner County residents have limited access to healthcare compared to the state as a whole. There are only 1.5 medical doctors per 1000 population compared to 2.4 per 1000 in all of Tennessee. There are only 1.9 hospital beds per 1000 population compared to 3.6 per thousand for Tennessee as a whole. 24,135 of Sumner County residents are enrolled in a TennCare MCO. This represents approximately 14% of the population. Until recently there was only a solitary, 2 OR outpatient multi-specialty ambulatory surgical treatment center in all of Sumner County. Just four months ago, the second one opened. There still is only one open and/or dedicated extremity MRI specialty scanner in all of Sumner County -- the subject of this application.

	Sumner (PSA)	Tennessee
<i>Current Year 2014, Age 65+</i>	25,164	981,984
<i>Projected Year 2018, Age 65+</i>	29,697	1,102,413
<i>Age 65+, % Change</i>	18.0%	12.3%
<i>Age 65+, % Total</i>	14.6%	14.9%
<i>2014 Total Population</i>	172,262	6,588,698
<i>2018, Total Population</i>	183,406	6,833,509
<i>Total Pop. % Change</i>	6.5%	3.7%
<i>TennCare Enrollees</i>	24,135	1,241,028
<i>TennCare Enrollees as a % of Total Population</i>	14.0%	18.8%

<i>Median Age</i>	38.7	38.0
<i>Median Household Income</i>	\$55,560	\$44,140
<i>Population % Below Poverty Level</i>	9.8%	17.3%

Source: TN Department of Health website, Bureau of TennCare, US Census Bureau

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: This existing open extremity scanner has proven to be both very convenient for patients, allowing them to have their diagnostic MRI scans in the same office as their doctor -- and often at the same visit -- and has also been of particular benefit to certain patients with special needs in regards to their care. It has been found to be especially helpful to all patients who are among the estimated 13-20% of the population that is claustrophobic (per American College of Radiology) or particularly anxious, patients with traumatic injuries or limited mobility for other reasons, obese patients, and anyone who benefits from the more open easy-access environment that an in-office scanner affords. In particular, we have found that children, and the elderly, have a much less stressful experience with scans performed in our setting where it is easier, more familiar, more personal, faster overall, and more convenient. We very rarely have had a patient who either cannot tolerate a scan in our Magnet or requires any kind of sedation to complete a study. Pediatric patients are able to have a scan with a parent right beside them literally holding their hands, which is easily accommodated with our scanner. It has also been our experience that patients who must otherwise take additional time off work, so they (or their children) can undergo MRI testing are very appreciative of not having to return for a scan on a different day. As might be expected, it is also our experience that this improves patient compliance.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

Response: The existing scanner at Southern Sports Medicine Institute is the only open scanner in all of Sumner County, and the only office based, specialty scanner in the service area as well. There simply are no other similar, office based, specialty, or open scanners in the service area.

There are four fixed whole body scanners in the service area, all owned and operated by Hospital facilities, which even a year ago (according to their actual submitted JAR reports, see below) were operating at 2,799 scans per scanner per year -- just barely below the need threshold average of 2,880 scans per fixed non-specialty scanner per year. There are no approved but unimplemented MRI CONs in the primary service area.

MRI Utilization**As Reported in Actually Filed JARs:**

	2011		2102		2013	
Portable MRI units	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>
Portland Diagnostic Center (1 day per week)		224		249		290
Specialty MRI units	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>
Southern Sports Medicine Institute		636		720		716
Fixed MRI units	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>	<u>Inpatient</u>	<u>Outpatient</u>
Sumner Regional Medical Center	371	2,207	540	2,051	922	1,948
Diagnostic Center at Sumner Station		1,413		1,707		4,090
TriStar Hendersonville Medical Center	688	1,678	800	1,567	777	1,788
Imaging Center at HMC		2,164		2,118		1,669
sub-total -- Fixed MRI procedures	1,059	7,462	1,340	7,443	1,699	9,495
Inpat + Outpat	8,521		8,783		11,194	
	2,130 avg. per unit		2,196 avg. per unit		2,799 avg. per unit	
Total Inpat. + Outpat. MRI Procedures	9,381		9,752		12,200	

Registry Data -- MRI Utilization of Tennessee Providers in Applicant's Service Area

Provider	Current # units (type)	County	Distance from SSMI (miles)	2011	2012	2013	% Change '11-'13	# MRI procedures by Sumner County residents (2013)
SSMI	1-fixed 0.2T	Sumner	0.0	636	720	716	12.6%	568
Sumner Station	1- fixed 1.5T	Sumner	6.9	1,403	1,688	1,922	37.0%	1,645
Hendersonville Medical Center	1- fixed 1.5T	Sumner	13	2,388	2,317	2,515	7.6%	1,849
Imaging Center at HMC	1- fixed 1.5T	Sumner	13	2,136	2,091	1,654	-22.6%	1,189
Portland Diagnostic	1-portable 1 day / wk	Sumner	14	221	245	285	29.0%	271
Sumner Regional Medical Center	1- fixed 1.5T	Sumner	0.1	2,544	2,560	3,008	18.2%	2,474
Total	6			9,278	9,621	10,100	8.9%	7,996

Source: Medical Equipment Registry - 12/22/2014

MRI Procedures per 1000 Population

	2011	2012	2013
Sumner	89.2	91.1	91.0
Macon	62.6	66.2	67.6
Smith	97.5	89.8	97.2
Trousdale	96.3	96.4	92.6
Statewide	87.2	87.7	86.0

Source: HSDA, US Census Population Estimates, Medical Equipment Registry - 12/22/2014

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion

of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology **must include** detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: Utilization for the past 3 years linearly projected into the next 2 years: (Projected volume assumes a similar rate of current utilization with a continued similar rate of growth.)

Scans	2012	2013	2014	2015	2016
SSMI open Extremity scanner	719	736	745	755	764

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)

- The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
- For projects that include new construction, modification, and/or renovation; **documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

Response: In conjunction with Southern Sports Medicine Institute, the project has already proven itself economically feasible, since its original CON implementation in 2004. Southern Sports Medicine is joining a group practice, which will now be the contracting provider of the service for SSMI, requiring this new CON.

PROJECT COSTS CHART

A. Construction and equipment acquired by purchase:		
1. Architectural and Engineering Fees		
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$ 30,000	
3. Acquisition of Site		
4. Preparation of Site		
5. Construction Costs		
6. Contingency Fund	\$ 50,000	
7. Fixed Equipment (Not included in Construction Contract)		
8. Moveable Equipment (List all equipment over \$50,000)		
9. Other (Specify) _____		
B. Acquisition by gift, donation, or lease:		
1. Facility (inclusive of building and land)	\$ 41,935	
2. Building only -		
3. Land only -		
4. Equipment (Specify) <u>greater of MRI lease or replacement</u>	\$500,000	
5. Other (Specify) _____		
C. Financing Costs and Fees:		
1. Interim Financing		
2. Underwriting Costs		
3. Reserve for One Year's Debt Service		
4. Other (Specify) _____		
D. Estimated Project Cost (A+B+C)		
	\$621,935	
E. CON Filing Fee	\$ 3,000	
F. Total Estimated Project Cost (D+E)		
TOTAL		\$624,935

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding **MUST** be inserted at the end of the application, in the correct alpha/numeric order and identified as **Attachment C, Economic Feasibility-2**.)

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ XX_E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other--Identify and document funding from all other sources.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Response: The project has already proven itself economically feasible. To allow the existing MRI services to continue, with the joining of Dr. Gautsch into AHP/ADI, this change to the named CON holder involves fairly minimal actual costs. The actual costs consist almost entirely of the costs of obtaining this new CON, and the costs which would be incurred as part of the ongoing provision of the already existant services otherwise. A cost to lease the MRI scanner and space it occupies are simply being attributed now to the applicant but will actually be charged back to Dr. Gautsch's care center. Dr. Gautsch has already fully paid for and depreciated the scanner, which has a residual market value of approximately \$100,000. Whether as SSMI or ADI, the scanner will need to be replaced in some future year. \$500,000 is a generous estimated cost to obtain a new replacement scanner when it becomes necessary. The space the scanner and its equipment occupy in the practice is approximately 308 sqft. To develop these project costs, another 61 sqft of waiting, bathroom and common space is being attributed to the scanning services, in proportion to the (number of scans)/(total number of patient visits) in the practice. The lease cost for the scanner is set at 6% or \$6000 per year, and the lease for the space set at \$12 per sqft/year, or \$4,430 per year. The initial term of the leases are 5 years, for a total of \$52,152 over 5 years. However, for the project cost calculation, \$41,935 (5.7% of the total building's appraised value, representing the 369 sqft portion of the building's space), plus the estimated cost of scanner replacement were used. The rest of the project cost is for filing, legal and contingency.

4. Complete Historical and Projected Data Charts on the following two pages--**Do not modify the Charts provided or submit Chart substitutions!** Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the **Proposal Only** (i.e., if the application is for additional beds, include anticipated revenue from the proposed

beds only, not from all beds in the facility).

Response: See below Projected Data Charts. The actual past 3 year average annual cost for service/maintenance of the scanner has been \$2,664 per year. It is projected to remain about the same for the next several years, paid separately from the lease, although a significant Contingency amount is also budgeted into the total project cost over the initial term. Since it is possible that the scanner will need replacement during that period of time, either with a used or new unit, for the Project Cost estimate the \$500,000 for a new similar unit including installation is accounted. That may not prove necessary during that period of time however since the unit remains in good shape.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Response: Average gross charge will be \$2107, average deduction from operating revenue will be \$1,489, and average net revenue will be \$618.

When SSMI joins Allied Health Partners (AHP), AHP's established fee schedule will replace SSMI's for all services. For extremity MRI scans AHP's average gross charge is \$2107, an approximately 34% increase from the very low \$1,570 average gross charge per scan at SSMI in 2013. Despite this change, the fee schedule charge per scan remains slightly less than the TN median MRI charge of \$2,175 as reported from the HSDA's equipment registry, and well below the average \$4,469 charged at other Sumner County facilities.

Although gross charges will increase, this change in fee schedule will have minimal actual impact on net revenues. With rare exception, all scans we perform are either provided as part of a bundled capitated payment, or reimbursed at pre-negotiated fixed contract rates, or according to state or federal payment schedules. Therefore actual net revenues have become independent of gross charges. Net revenues are much more influenced by the contracting and effectiveness of a group's billing department at successfully navigating through the tedious and complicated process of insurance company follow-up, to track and ensure contracted reimbursements for provided services are all actually received.

January 23, 2015**12:41 pm****HISTORICAL DATA CHART**

Give information for the last *three (3)* years for which **complete data** are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2011	Year 2012	Year 2013
A. Utilization Data (Specify unit of measure)	636	720	723
B. Revenue from Services to Patients			
1. Inpatient Services	\$ -	\$ -	
2. Outpatient Services	\$ 815,383	\$ 935,674	\$1,135,395
3. Emergency Services	\$ -	\$ -	\$ -
4. Other Operating Revenue (Specify)	\$ -	\$ -	\$ -
Gross Operating Revenue	\$ 815,383	\$ 935,674	\$ 1,135,395
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	\$ 521,017	\$ 563,878	\$ 776,243
2. Provision for Charity Care	\$ 4,000	\$ 4,000	\$ 4,000
3. Provisions for Bad Debt	\$ 32,615	\$ 37,427	\$ 45,416
Total Deductions	\$ 557,632	\$ 605,305	\$ 825,659
NET OPERATING REVENUE	\$ 257,751	\$ 330,369	\$ 309,736
D. Operating Expenses			
1. Salaries and Wages	\$ 25,751	\$ 51,567	\$ 46,236
2. Physician's Salaries and Wages	\$ -	\$ -	\$ -
3. Supplies	\$ 887	\$ 861	\$ 135
4. Taxes	\$ 975	\$ 832	\$ 1,020
5. Depreciation	\$ -	\$ -	\$ -
6. Rent	\$ 5,042	\$ 5,042	\$ 5,042
7. Interest, other than Capital	\$ -	\$ -	\$ -
8. Management Fees:			
a. Fees to Affiliates	\$ -	\$ -	\$ -
b. Fees to Non-Affiliates	\$ 43,605	\$ 48,535	\$ 52,955
9. Other Expenses (Specify) <u>See Attached</u>	\$ 11,120	\$ 2,473	\$ 5,809
Total Operating Expenses	\$ 87,380	\$ 109,310	\$ 111,198
E. Other Revenue (Expenses) – Net (Specify)			
NET OPERATING INCOME (LOSS)	\$ 170,371	\$ 221,059	\$ 198,538
F. Capital Expenditures			
1. Retirement of Principal	\$ -	\$ -	\$ -
2. Interest	\$ -	\$ -	\$ -
Total Capital Expenditures	\$ -	\$ -	\$ -
NET OPERATING INCOME (LOSS)			
LESS CAPITAL EXPENDITURES	\$ 170,371	\$ 221,059	\$ 198,538

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2015	Year 2016
A. Utilization Data (Specify unit of measure)	726	730
B. Revenue from Services to Patients		
1. Inpatient Services	\$ -	
2. Outpatient Services	\$ 1,529,334	\$ 1,537,760
3. Emergency Services	\$ -	
4. Other Operating Revenue (Specify)	\$ -	
Gross Operating Revenue	\$ 1,529,334	\$ 1,537,760
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	\$ 1,015,809	\$ 1,021,428
2. Provision for Charity Care	\$ 4,000	\$ 4,000
3. Provisions for Bad Debt	\$ 61,173	\$ 61,510
Total Deductions	\$ 1,080,982	\$ 1,086,938
NET OPERATING REVENUE	\$ 448,351	\$ 450,821
D. Operating Expenses		
1. Salaries and Wages	\$ 46,428	\$ 46,684
2. Physician's Salaries and Wages	\$ -	
3. Supplies	\$ 136	\$ 137
4. Taxes	\$ 1,024	\$ 1,030
5. Depreciation	\$ -	
6. Rent	\$ 4,430	\$ 4,430
7. Interest, other than Capital	\$ -	
8. Management Fees:		
a. Fees to Affiliates	\$ 134,505	\$ 135,246
b. Fees to Non-Affiliates	\$ -	\$ -
9. Other Expenses (Specify) <u>MRI lease., Ins., Data</u>	\$ 33,253	\$ 33,376
Total Operating Expenses	\$ 219,776	\$ 220,903
E. Other Revenue (Expenses) – Net (Specify)		
NET OPERATING INCOME (LOSS)	\$ 228,575	\$ 229,918
F. Capital Expenditures		
1. Retirement of Principal	\$ -	
2. Interest	\$ -	
Total Capital Expenditures	\$ -	\$ -
NET OPERATING INCOME (LOSS)		
LESS CAPITAL EXPENDITURES	\$ 228,575	\$ 229,918

PROJECTED DATA CHART **

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year **
A. Utilization Data (Specify unit of measure)	740
B. Revenue from Services to Patients	
1. Inpatient Services	
2. Outpatient Services	\$ 1,558,825
3. Emergency Services	
4. Other Operating Revenue (Specify) _____	
Gross Operating Revenue	\$ 1,558,825
C. Deductions from Gross Operating Revenue	
1. Contractual Adjustments	\$ 1,035,475
2. Provision for Charity Care	\$ 4,000
3. Provisions for Bad Debt	\$ 62,353
Total Deductions	\$ 1,101,828
NET OPERATING REVENUE	\$ 456,997
D. Operating Expenses	
1. Salaries and Wages	\$ 47,323
2. Physician's Salaries and Wages	
3. Supplies	\$ 139
4. Taxes	\$ 1,044
5. Depreciation	
6. Rent	\$ 4,430
7. Interest, other than Capital	
8. Management Fees:	
a. Fees to Affiliates	\$ 137,099
b. Fees to Non-Affiliates	\$ -
9. Other Expenses (Specify) <u>Ins., Data</u>	\$ 24,712
Total Operating Expenses	\$ 214,747
E. Other Revenue (Expenses) – Net (Specify)	
NET OPERATING INCOME (LOSS)	\$ 242,250
F. Capital Expenditures	
1. Retirement of Principal	\$ 91,396
2. Interest	\$ 22,500
Total Capital Expenditures	\$ 113,896
NET OPERATING INCOME (LOSS)	
LESS CAPITAL EXPENDITURES	\$ 128,354

** Some future year when the scanner requires replacement with a similar system

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Response: Charges will average \$2,107 per extremity scan, following the Advanced Health Partners Fee Schedule.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response:

Charges:	CPT 73221	CPT 73721
This practice	\$2,087	\$2,126
Sumner Regional Medical Center	\$4,731	\$4,731
Hendersonville Medical Center	\$4,953 Avg.	

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Response: Utilization rates have been fairly stable and slowly increasing over the course of many years. Generated by the group's providers, they are more than sufficient to maintain financial viability and cost-effectiveness. As an office based, permanent magnet scanner, the project has low fixed costs compared to many other facilities. Our principle costs are the staff member's time given to the scanner, and the Radiologist's read -- variable costs associated with each scan. So, with the normal ebb and flow of patient volume week to week, or even an unlikely significant down-turn, expenses fall proportionately, and providing in-office MRI scanning still remains both cost effective and very convenient for our patients.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Response: The project's existing services are already financially viable. The scanner has already been fully paid and depreciated. The space the scanner and its equipment occupy in the practice is approximately 308 sqft. Another 61 sqft of waiting, bathroom and common space is being attributed to the scanner, in proportion to the (number of scans)/(total number of patient visits). Fixed costs are relatively low. The lease cost for the scanner at 6% is \$6000 per year, and the lease for the space at \$12 per sqft per year is \$4,430 per year. The principle variable costs are the costs of the tech that operates the scanner and a small amount for the scheduling and billing, which are performed in conjunction with the practice. There are reading fees associated with each scan of approximately \$100 per scan, and low supply and other costs. The revenues generated by the scans more than cover total costs. See the Projected Data Chart.

January 23, 2015**12:41 pm**

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Response: In 2013, 15.9% of the scans performed were for Medicare patients. 9.3% of the scans performed were for TennCare patients insured by United Healthcare Community Plan (Americhoice), the largest TennCare MCO in the region, the only TC MCO which Southern Sports Medicine Institute has contracted with. Preliminary 2014 data shows slight increases in both at MC 17.7% and TC 11.6%. As a part of ADI, and its expanded number of contracts, including with Amerigroup BlueCare, and TennCare Select, the number of TennCare patients that will utilize the scanner will likely increase.

For the past 18 years, Dr. Gautsch and Southern Sports Medicine Institute have provided emergency orthopedic surgical care to medically indigent patients whenever asked to do so as specialists on call. Additionally, medically indigent patients are also seen at SSMI for elective orthopedic care through the Sumner County Salvus Center as one of its panel specialists. The Salvus Center was established by physicians and several community leaders in conjunction with the then, not for profit local hospital in Gallatin, in order to provide coordinated and comprehensive care for the medically indigent of Sumner County. Services are provided for a small fee based on a sliding scale and ability to pay.

Each of the participant providers provides discounted care in their specialty, with the community hospital having agreed to provide MRI scans, among other discounted services, with interpretation for \$50 per scan. A few years ago, when the local hospital was sold and converted into a for-profit facility, one of the Sumner County Commission's stipulations to that sale was a continuation of the Salvus Center arrangement. Both Sumner County hospitals now participate in the program similarly.

At present, virtually all medically indigent patients in Sumner County needing MRI scans obtain them through this program at one of the four fixed whole body scanners. Charity scans have been provided at SSMI as necessary for those few patients who were unable to be scanned through Salvus for some reason, or could/would not participate in the Salvus Center. However, the Salvus program is quite robust and therefore typically only about 4 charity scans per year have come to us.

Historical and Projected Service Payor Mix

Payor Source	2013 SSMI Gross Revenue (as a % of total)	Year 1 Applicant's Projected Gross Revenue	Year 1 Gross Revenue by Payor Source as a % of total
Medicare	17.7%	\$270,692	17.7%
TennCare	11.6%	\$177,403	11.6%
Managed care	10.3%	\$157,521	10.3%
Commercial	57.6%	\$880,896	57.6%
Self-Pay	0.5%	\$7,647	0.5%
Other	2.3%	\$35,175	2.3%
Total	100.0%	\$1,529,334	100.0%

10. Provide copies of the balance sheet and income statement from the most recent reporting period

of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

Response: See attached.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Response: The only possible alternatives to this practice associated project are either to bring the practice into ADI and discontinue existing MRI services, shifting the volume to other existing scanners in the service area, which were operating at average 2,800 scans per year in 2013 -- already at just below the 2,880 need threshold -- with great inconvenience and additional expense to patients and insurers. Or, not merge the practice, with the risk that failing to adjust to changes in Healthcare provision could ultimately lead to practice instability and financial failure. Resulting in: discontinuance of existing MRI services, shifting the volume to other existing scanners in the service area, which are operating at average 2,800 scans per year in 2013 -- already at just below the 2,880 need threshold -- with great inconvenience and additional expense to patients and insurers.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Response: This proposal seeks continuance of existing MRI services after practice merger, with the only Open and only Extremity MRI scanner, in a service area in which the fixed whole body scanners are likely operating well above threshold levels, without any need for new construction or even renovation. There is no superior alternative except perhaps to later seek an ODC designation to allow physicians from outside the group to refer patients to this scanner as an alternative to the over-utilized other scanners in the service area.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

Response: The applicant and its physician members have contracts with the vast majority of insurers, managed care organizations and networks operating in the service area including principally Blue Cross Blue Shield, Cigna, United Healthcare, Aetna, Humana, Americhoice, Amerigroup, BlueCare, HealthSprings Medicare Advantage plans, QCMN IPA. It also has contracts to provide physician professional and/or on-call services for Sumner Regional Medical Center, Hendersonville Medical Center, Middle Tennessee Imaging, LLC d/b/a Premier Radiology, St. Thomas Hospital (all locations), University Medical Center, and Williamson Medical Center.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: This proposal seeks continuance of existing MRI services after practice merger, with the only Open MRI scanner in a service area in which the other fixed whole body scanners are operating near or above threshold levels. There is no duplication of existing services or new competition arising from this proposal. It is projected to have no discernable effect on the utilization rates of other existing providers in the service area of the project.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: As an office based scanner, the patients undergoing MRIs as a part of their care are already attended by the physicians and medical office staff, present for the operation of the office as a whole, including the receptionist, nurses and billing staff. There are approximately 10,000 patient visits to the office per year, only approximately 720 of them include a 60 minute MRI scan visit. A small percentage of the staff activity is attributable to additional care of the patients undergoing scans. In addition there is an office Radiology Technician who operates the scanner and directly supervises the patient during scans. This Tech also performs other responsibilities for the practice and so, only time spent with patients undergoing MRI scans is attributed to the MRI service, less than a single FTE at a pay rate of \$17.50/hr. This rate is less than average for a dedicated MRI Tech in the TN workforce, but consistent with our area and the principle responsibilities in this office for this individual, who has been in this position for over 7 years.

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Response: As an existing office based scanner, availability and accessibility to human resources is already in place, including adequate professional staff. With the merger, even better and more fully developed Human resources will be available.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

Response: The applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Response: N/A

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental

Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

Response: The current MRI services are already compliant with the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and Medicare requirements as applicable. The applicant has also reviewed and understands these requirements.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Response:

Licensure: None is offered to this practice-based project.

Accreditation: The Intersocietal Commission for the Accreditation of Magnetic Resonance

Laboratories (ICAMRL) has already accredited this scanner once. Its second accreditation is pending. See attached certificate.

SSMI was the first scanner in Sumner County to receive Independent Accreditation, many payors now require it.

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Response: N/A

d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Response: N/A

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Response: None

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project

Response: None

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Response: If the proposal is approved, the applicant will continue to provide the Tennessee Health Services and Development Agency and/or the reviewing agency requested information

concerning the number of patients treated, the number and type of procedures performed, and other data as required.

-000-

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other

projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.

Response: See below.

2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

Response: N/A

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68-11-1609(c): _____

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

<u>Phase</u>	<u>DAYS REQUIRED</u>	<u>Anticipated Date (MONTH/YEAR)</u>
1. <u>Architectural and engineering contract signed</u>	_____	_____
2. <u>Construction documents approved by the Tennessee Department of Health</u>	_____	_____
3. <u>Construction contract signed</u>	_____	_____
4. <u>Building permit secured</u>	_____	_____
5. <u>Site preparation completed</u>	_____	_____
6. <u>Building construction commenced</u>	_____	_____
7. <u>Construction 40% complete</u>	_____	_____
8. <u>Construction 80% complete</u>	_____	_____
9. <u>Construction 100% complete (approved for occupancy)</u>	_____	_____
10. <u>*Issuance of license</u>	_____	<u>Will not require license</u>
11. <u>*Initiation of service</u>	_____	<u>March 1, 2015</u>
12. <u>Final Architectural Certification of Payment</u>	_____	_____
13. <u>Final Project Report Form (HF0055)</u>	_____	_____

* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF

TN

COUNTY OF

Sumner

Thomas L. Gautsch, Jr., being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.



SIGNATURE/TITLE

Sworn to and subscribed before me this 13th day of Jan., 2015 a Notary
(Month) (Year)

Public in and for the County/State of Sumner / Tennessee.



Toni M. Stephens
NOTARY PUBLIC

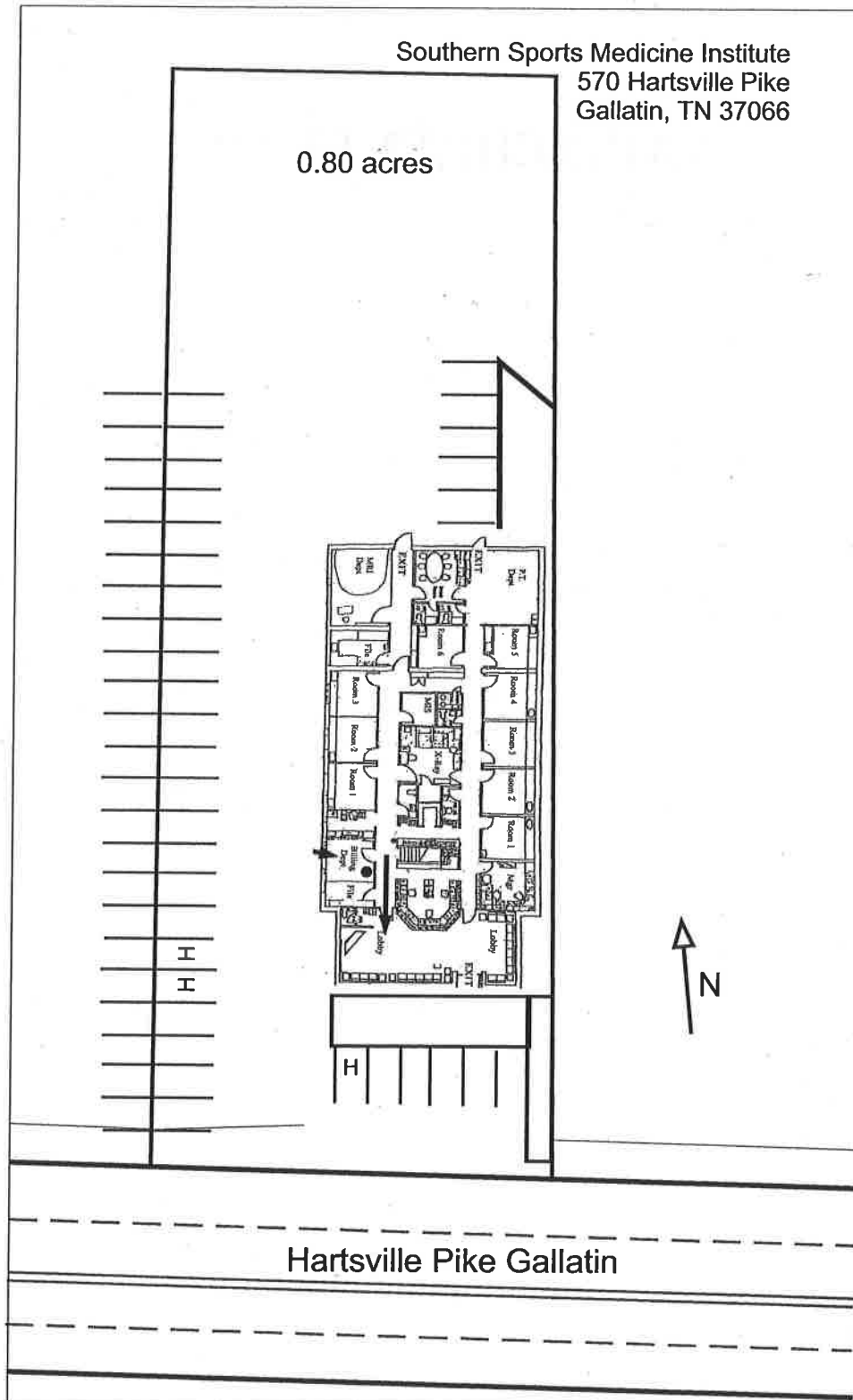
My commission expires

12/17
(Month/Day)

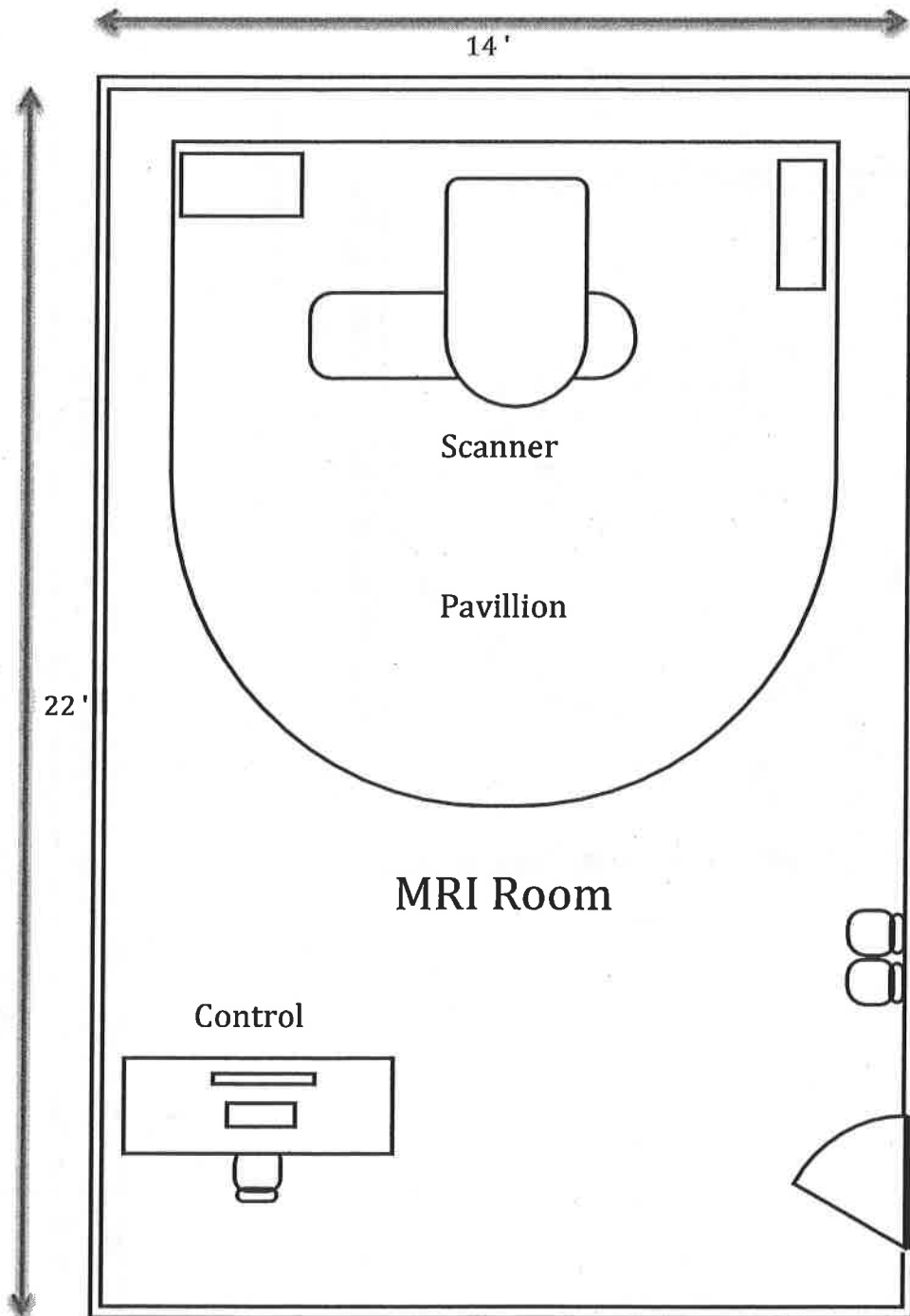
2018
(Year)

ATTACHMENTS

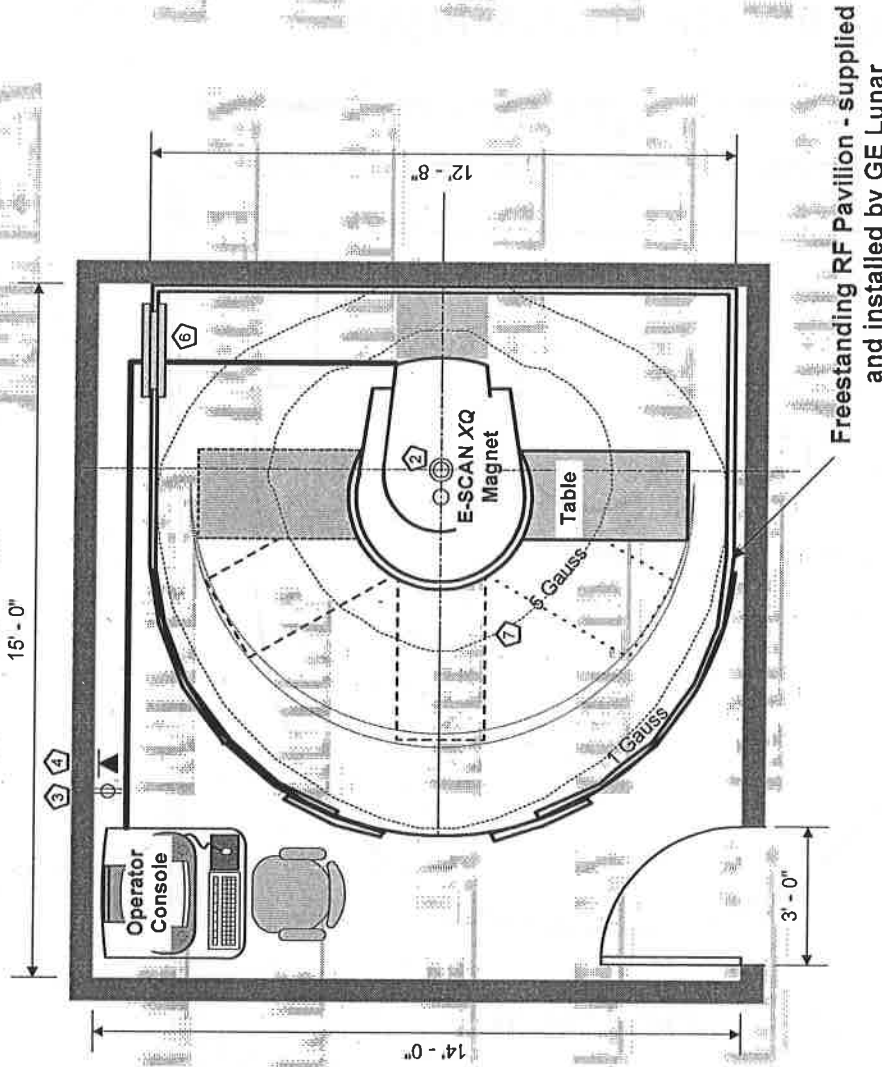
ATTACHMENT B.III.(A)1
COPY OF PLOT PLAN



ATTACHMENT B.IV
COPY OF FLOOR PLAN



MRI Room 308 sqft., contains scanner and its equipment
(An additional 61 sqft. is attributed from common space.)



KEY

- 2) MAGNET ISOCENTER
- 3) TELEPHONE LINE REQUIRED FOR SERVICE MODEM
- 4) DEDICATED 110VAC, 20AMP GROUNDED OUTLET REQUIRED
- 5) GE LUNAR SUPPLIED RF PENETRATION PANEL
See Pg. 14 Fig 2-4 in the Site Planning Guide for actual dimensions
- 5 GAUSS LINE: EXCLUSION ZONE FOR PERSONS WITH PACEMAKERS OR OTHER BIOMEDICAL IMPLANTS

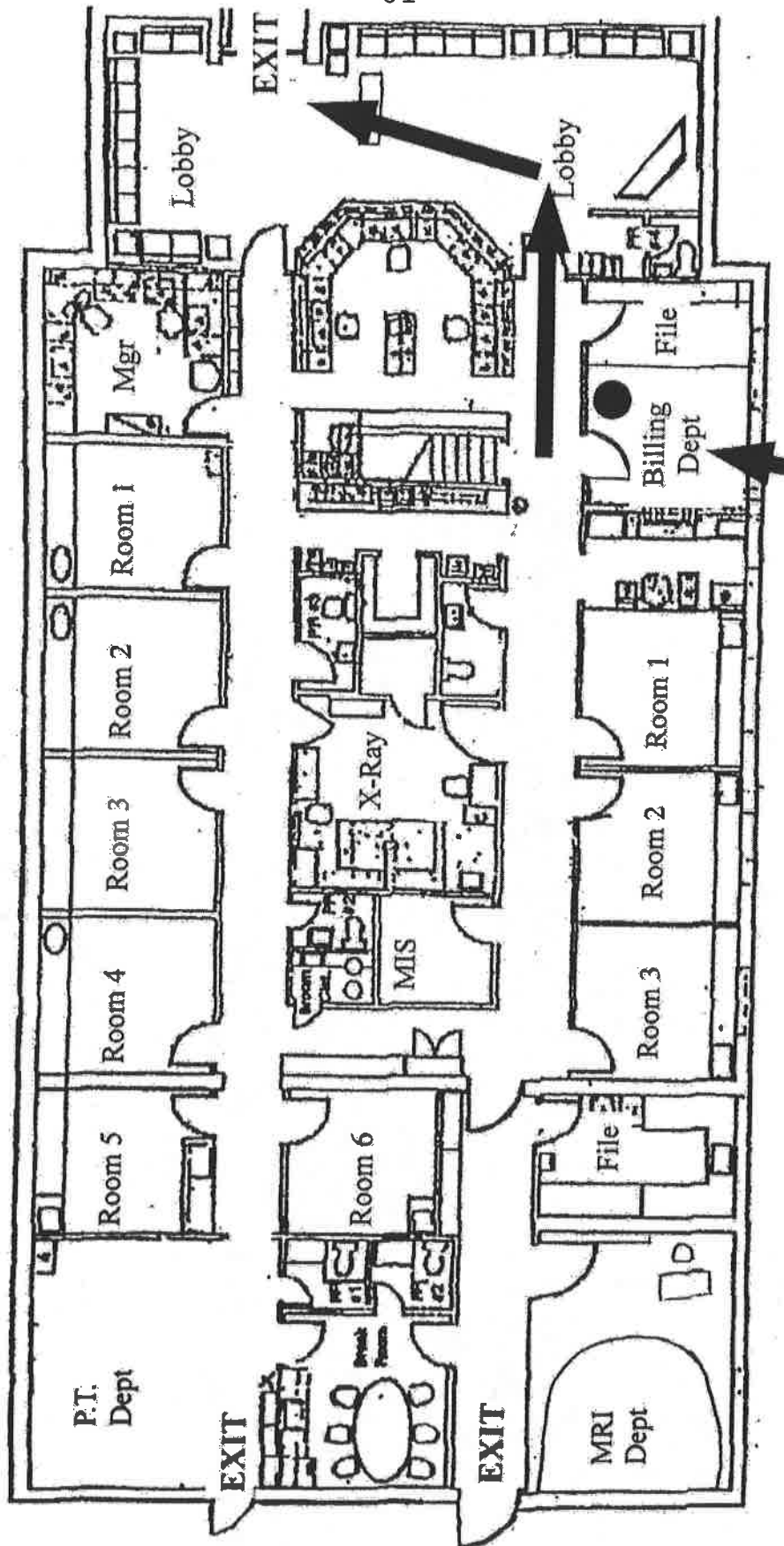
Typical E-SCAN XQ Layout - Sample Pavilion Layout



GE LUNAR CORP
726 Heartland Trail
MADISON, WI 53717
Phone: (608) 828-2663
Fax: (608) 828-7105

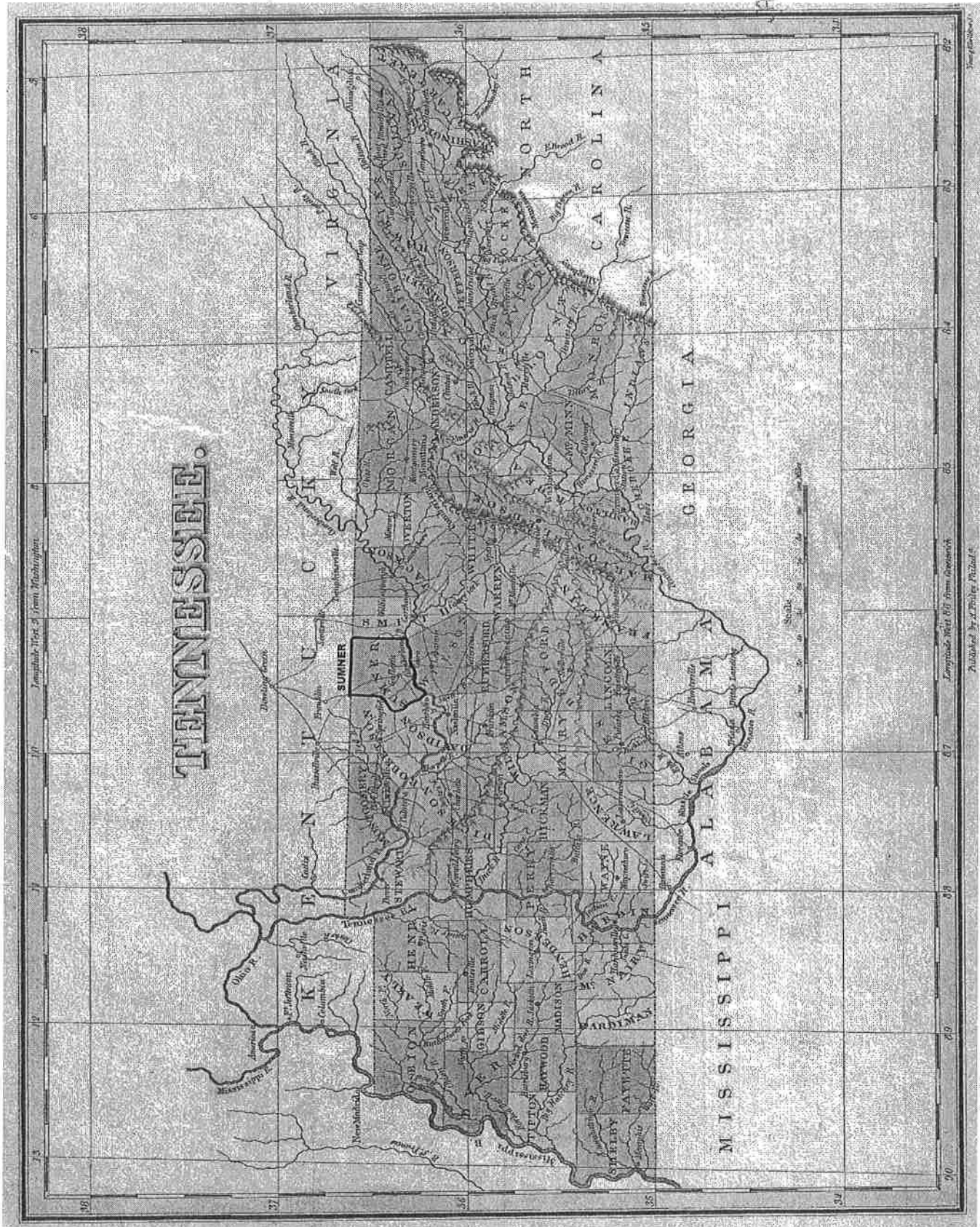
Key	
	Window
	Existing wall
	New wall
	RF screened wall

Sample	NS 00/00/00 1/4" = 1' - 0"
Please Sign and Date For Your Approval:	
Initials:	_____
Date:	_____



ATTACHMENT C. NEED - 3
MAP OF SERVICE AREA

AN 1415 03:35



Attachment Section C, Economic Feasibility, Item 4

OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	<u>Year 2011</u>	<u>Year 2012</u>	<u>Year 2013</u>
1 Expensable Capital Purchases	\$1,640	\$268	\$-
2 Janitorial Service	\$404	\$430	\$420
3 Pest Control	\$39	\$48	\$49
4 Total Insurance	\$3,368	\$210	\$249
5 Licenses and Permits	\$2,400	\$-	\$1,200
6 Postage and Delivery	\$287	\$167	\$98
7 Printing and Reproduction	\$61	\$-	\$72
8 Service Repairs & Maintenance	\$2,922	\$1,350	\$3,721
Total Other Expenses	\$11,120	\$2,473	\$5,809

**ATTACHMENT C,
ECONOMIC FEASIBILITY – 10
INCOME STATEMENT AND BALANCE SHEET**

Advanced Diagnostic Imaging, PC
Income Statement

Period and Year to Date Compare to Last Year w/Percents
For the Period from October 1, 2014 to October 31, 2014

	Current Period		Year to Date		Last Year to Date	
Revenue						
Professional Fees	5,251,142	101%	41,386,000	101%	24,001,208	101%
Refunds	-43,602	-1%	-350,294	-1%	-173,542	-1%
Net Professional Fees	5,207,541	100%	41,035,707	100%	23,827,666	100%
Professional Fees - Premier Rad.	787,274	15%	3,359,283	8%	3,859,758	16%
Other Revenue	47,817	1%	474,926	1%	168,058	1%
Total Revenues	6,042,631	116%	44,869,916	109%	27,855,482	117%
Operating Expenses						
Staff Compensation	798,119	15%	6,517,993	16%	2,559,308	11%
Staff Physician Compensation	1,799,763	35%	13,964,561	34%	6,089,372	26%
General & Administrative Expenses	459,043	9%	3,933,910	10%	2,217,973	9%
Billing & Collections	351,727	7%	3,001,491	7%	2,302,507	10%
Teleradiology	25,003	0%	715,947	2%	322,095	1%
Insurance - Malpractice	60,470	1%	753,381	2%	527,985	2%
Non Operating Income & Expenses	20,208	0%	211,866	1%	85,295	0%
Total Operating Expenses	3,514,333	67%	29,099,148	71%	14,104,536	59%
Available for owners income	2,528,299	49%	15,770,768	38%	13,750,946	58%
Owners Compensation						
Owner Compensation	1,049,318	20%	10,564,300	26%	9,871,874	41%
Owner Bonuses	1,710,338	33%	3,054,755	7%	1,204,505	5%
Total Owners Compensation	2,759,656	53%	13,619,055	33%	11,076,379	46%
Owners Income / <Loss>	-231,358	-4%	2,151,713	5%	2,674,567	11%
Total Expenses	6,273,989	120%	42,718,203	104%	25,180,916	106%

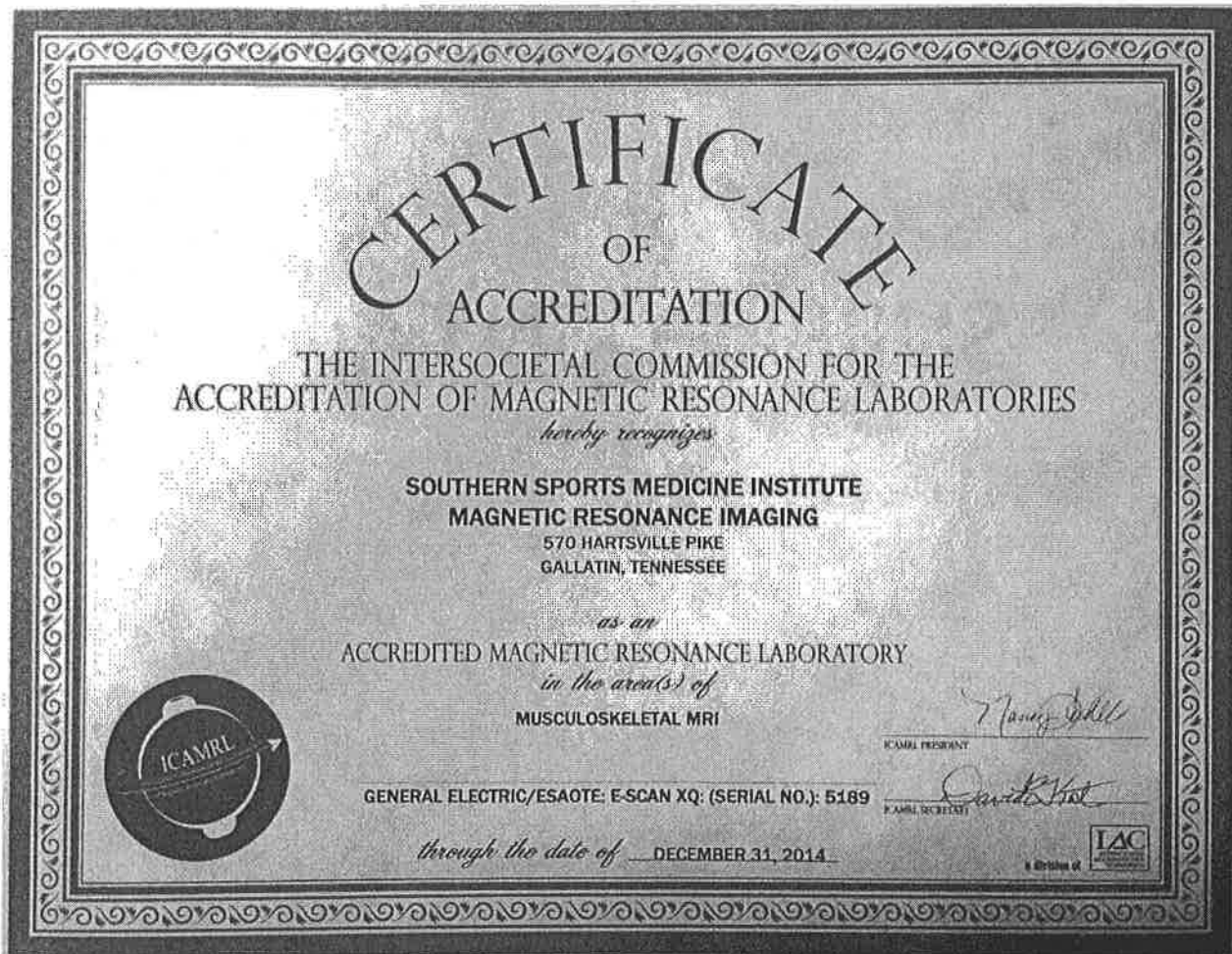
Advanced Diagnostic Imaging, PC**Balance Sheet****October, 2014**

	Balance
ASSETS	
Current Assets	
Cash Operating	1,952,131
Intercompany - Rec. / <Payable>	66,079
Other Current Assets	21,655
Total Current Assets	2,039,865
Fixed Assets	
Leasehold Improvements	79,820
Equipment - Net	647,160
Net Fixed Assets	726,980
TOTAL ASSETS	2,766,845
LIABILITIES AND EQUITY	
Current Liabilities	
Accounts Payable	202,865
Other Accrued Expenses	68,643
Other Current Liabilities	108,994
Total Current Liabilities	380,502
Notes and Loan Payables	
Funds Transferred from Subsidiaries	305,000
Deferred Revenue	83,565
Total Long-Term Liabilities	388,565
Total Liabilities	769,068
Total Equity	1,997,778
TOTAL LIABILITIES AND EQUITY	2,766,845

Section C, Contribution to the Orderly Development of Healthcare, 7 (b)

Accreditation

JAN 25 2015



SUPPLEMENTAL #1

January 23, 2015**12:41 pm**

January 22, 2015

Philip Grimm, MHA
HSDA Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th floor,
502 Deaderick St.
Nashville, TN 37243

RE: Certificate of Need Application CN1501-002
Advanced Diagnostic d/b/a Southern Sports Medicine Institute

Dear Mr. Grimm,
Following are the responses to your January 16 set of supplemental questions:

1. Section A, Item 3 and Published LOI

It appears that the name – Southern Sports Medicine Institute - was omitted from the published LOI in lieu of the name identified in Section A, Item 1, page 1 and the name noted in the executive summary of the project on pages 5 and 6 of the application (Advanced Diagnostic Imaging P.C d/b/a Southern Sports Medicine Institute). Given the applicant's plans to secure approval of the CON under its name and retain as much public recognition as possible of the existing MRI service, please clarify by confirming the name of the applicant.

Response: The applicant is Advanced Diagnostic Imaging, P.C.

ADI seeks to replace Thomas L. Gautsch, MD, PC, to whom the existing MRI CON is granted, to continue "in-office magnetic resonance imaging (MRI) services utilizing a GE Lunar E-scan 0.2 Tesla open dedicated MRI for extremity scanning in the office of and in conjunction with the practice of Southern Sports Medicine Institute". After joining the multi-specialty group ADI, SSMI will be one of the individual care centers that constitute the private group practice ADI. Southern Sports Medicine Institute will remain the name of the facility, becoming a d/b/a name of ADI.

Review of the information on file for ADI with the Secretary of State's office revealed several assumed names in calendar year 2103 such as The Hand Center, Pinnacle Surgical Partners, Advanced Orthopaedic and Spine and Advanced Cardiovascular & Thoracic Surgery. Please identify all active ADI sites in TN with names & addresses that provide MRI services (as of January 2015).

Response: ADI currently does not have any sites that provide MRI services. Dr. Gautsch's office location will be the first site offering such services.

January 23, 2015**12:41 pm**

Review of the state website and Goggle Search also points to what appears to be a potential organizational linkage between ADI and Premier Radiology. If applicable, please briefly describe the relationship and identify the names and addresses of all Premier sites with MRI in TN (if different from the list requested for ADI). It would be helpful to include an organizational chart with your response to further illustrate the organizational relationship between the parties.

Response: ADI and Premier are legally separate organizations. ADI provides professional interpretations for imaging studies performed at some of the Premier Radiology locations via a professional services agreement. Some of the radiologists who practice at ADI also have indirect ownership in Middle Tennessee Imaging, LLC d/b/a Premier Radiology.

Please see attached Organizational Chart.

Please see attached list of the Premier Radiology sites that provide MRI services.

2. Section A, Item 6

The attachment of the signed lease 1/9/2015 agreement of the 308 square foot office space at 570 Hartsville Pike in Gallatin, TN between Dr. Gautsch (landlord) and Advanced Diagnostic Imaging, P.C. (tenant) is noted. In your response, please also provide a copy of the tile or deed to the property, recent tax record or like item that documents the landlord's (Thomas L. Gautsch, MD) ownership of same.

Response: Please see the attached Tax record.

3. Section A, Item 8

The response is noted.

As described in the Letter of Intent & other parts of the application, the existing MRI service approved in CN0110-088A will continue operating as a private physician practice. Given the potential for allowing a broader scope of patients within SSMI's service area as a result of joining ADI and participating in its 3rd party payor networks, does the project include MRI services for all patients of the multi-specialty physicians associated with ADI, in addition to those currently registered with SSMI? Please clarify. In your response, please identify the names & specialties of physician members/employees of ADI that are expected to refer patients to the applicant's Gallatin location for extremity MRI services.

Response: At this time, with the exception of Dr. Gautsch, there are not specific physicians employed by ADI who are expected to refer MRI services to the SSMI location. Other than Dr. Gautsch, there is only one other ADI multi-specialty physician practicing in a different part of Sumner County who may have use for the extremity scanner. However, referral patterns would make it unlikely that this other provider would use the scanner at Dr. Gautsch's office.

4. Section A, Project Description, Item 13

The increase in participation in all active TennCare MCOs as a result of joining ADI is noted. Since an immediate benefit of the project appears to be interpretation of extremity MRI images by any or all of the 37 radiologists employed by ADI, please describe the arrangement planned for billing of their professional fees for interpretation of the applicant's extremity MRI images as it pertains to their participation in the TennCare MCOs noted in the applicant's response. If billing separately, it would be helpful to include names, medical and provider license numbers of the radiologists involved in this regard.

Response: Once Dr. Gautsch joins ADI, ADI will bill for the services of the MRI, as it will bill for all other services performed by Dr. Gautsch. Because Dr. Gautsch will be part of the same provider as the reading radiologists, all MRI studies will be billed globally to include both the technical and professional portions of the imaging services.

5. Section B, Project Description, Item I.A

Based on the comments provided in the 3rd paragraph of the executive summary (page 6), Dr. Gautsch, an Orthopaedic Surgeon, a new replacement physician to be hired in the near future and a non-physician provider are expected to order extremity MRI imaging for the existing scanner. Please briefly explain how the referrals of the non-physician provider apply in this regard. Please also briefly describe how the scope of the project might be broader as a result of increased referrals by multi-specialty physician employees of ADI located throughout the Middle-Tennessee area.

Response: SSMI has at various times employed Physician Assistant providers in the practice. It is anticipated that a future PA working with Dr. Gautsch and/or a new future physician provider would also order scans utilizing this MRI scanner. As noted in question 3 above, at this time, it is not anticipated that other ADI multi-specialist physicians will refer to the scanner in Dr. Gautsch's office.

6. Section B, Project Description, Item II.E (MRI Equipment)

Note: as a suggestion, it would help to attach the vendor quote for purchase of the agreement as documentation of the response for this item in lieu of providing it as documentation for Section C, Economic Feasibility, Item 8 on page 28 of the application. Please provide a replacement cover page for the vendor's equipment quote labeled as Section B, Project Description, Item II.E.

Item II.E.3 – the description of primary and occasional MRI applications by standard CPT code and plans for imaging interpretation support by board certified radiologists of ADI are noted. Please confirm that the radiologists that interpret the applicant's MRI images are actively licensed Tennessee physicians.

Response: The ADI radiologists that will interpret the applicant's MRI images are all actively licensed Tennessee physicians, board certified in radiology.

There is a reference on page 28 to a \$100 cost per scan for imaging interpretation services, which might equate to an annual cost of \$72,600 in Year 1 of the project. As such, please briefly describe the arrangement planned for covering the costs of professional imaging interpretation fees, including billing of same by ADI, as appropriate.

Response: As noted in question 4 above, ADI will globally bill the MRI services performed in Dr. Gautsch's office to include both the technical and professional components of the MRI imaging. For the purposes of the Projected data chart, an estimate of the average professional portion of the globally billed services is provided as "fees to affiliates" since they are replacing the "fees to non-affiliates", the radiologists who currently read the studies at a per study cost of \$85 - \$100 per study. The annual cost listed in the Historical Data Chart is exclusive of those government funded programs which require the radiologists to bill for their services directly.

7. Section C, Need, Item 1 (Specific Criteria, Magnetic Resonance Imaging, (MRI))

The responses are noted. Please provide clarification for the following items:

Item 5.b.

Given the historical utilization in excess of 85% of capacity provided in the response, was downtime of the unit taken into consideration?

Response: Yes. Although following the 5.b criteria calculates a utilization in excess of 85%, one experienced additional benefit of this Doctor office based MRI service is the easy ability to expand or contract hours or days of operation to match patient and physician needs by simply shifting job responsibilities internally.

Item 7.b

What existing documentation might help document safety of the unit such as satisfactory compliance with city or county requirements? Given the age of the unit, what plans does ADI have to inspect and document the safety of the physical environment before or shortly after its merger with SSMI?

Response: Standard internal tests are run on the scanner prior to every day of operation. Additionally, regular periodic maintenance, and recalibration if necessary, is performed. The next most comprehensive scheduled evaluation will be in Feb. 2015. ADI will inspect the physical environment for safety.

Item 7.f

Please identify the ICAMRL accreditation type. Does ADI also maintain accreditation with this organization at its MRI locations in Middle Tennessee? Please clarify.

Response: Our ICAMRL accreditation was granted in the area of Musculoskeletal MRI. As noted above, ADI does not offer imaging at any of its other locations.

There are two primary MRI accrediting bodies recognized by CMS and many insurers – the American College of Radiology (ACR) and the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL). Both primary accreditation programs feature credentialing requirements for medical staff, clinical image quality requirements, equipment performance standards, and quality control measures. When a facility passes MRI accreditation, the site is awarded a three-year certification. Premier Radiology Locations are ACR accredited. Most Radiology groups seek accreditation through the ACR, their professional body. Most Orthopedic practices with office based MRI scanners seek accreditation by ICAMRL, since the American Academy of Orthopaedic Surgeons is one of its sponsoring organizations.

Representatives from these below organizations make up the IAC MRI Board of Directors:

BOARD OF DIRECTORS & SPONSORING ORGANIZATIONS

- American Academy of Orthopaedic Surgeons (AAOS)
- American Academy of Neurology (AAN)
- American College of Cardiology (ACC)
- American Society of Neuroimaging (ASN)
- American Society of Radiologic Technologists (ASRT)
- International Society for Musculoskeletal Imaging in Rheumatology (ISEMIR)
- Society for Cardiovascular Magnetic Resonance (SCMR)

8. Section C, Need, Item 2 and Section C, Economic Feasibility, Item 11

The responses are noted. In terms of development plans and given the multi-specialty nature of ADI, was any consideration given to requesting that the limitation to extremities in CN0110-088A be lifted as part of the project in lieu of having to request same in the future? Please explain.

Response: It is our understanding that restriction in terms of extremity only scanning mostly relates to the fact that the scanner located at the SSMI location is only capable of doing extremity scanning. If at some point in the future it becomes necessary to replace the scanner at this location, it may make sense to replace it with a more modern scanner that is capable of scanning other parts of the body. With this in mind, it may be most efficient to remove this restriction from the CON at this time to reduce the administrative burden of having to approach the HSDA later. Of course unless and until the scanner is replaced, only extremities will be scanned because that is all that the scanner is capable of doing. There are no current plans to replace the scanner.

9. Section C, Need, Item 5

The 2 tables documenting MRI utilization trend of Sumner County providers are noted. Regarding utilization reported in the JAR table, what accounts for the significant difference between the Sumner Station's MRI utilization for 2013 (4,090) and the utilization per HSDA Equipment registry records (1,922 MRI procedures).

January 23, 2015**12:41 pm**

Given ADI's existing operations in other MRI sites in Middle Tennessee, please identify utilization of each site by completing the table below using MRI procedures documented in the HSDA Equipment Registry.

Response:

Please see attached relevant pages from the SRMC 2013 JAR demonstrating their reported number of MRI procedures in 2013. The reasons for the discrepancy between the HSDA Equipment Registry data and the SRMC submitted JAR is unclear. However, there have been significant changes to large provider networks in that approximate time-frame, in particular the Blue S Network, for which SRMC remains an in-network provider while Tri-Star facilities no longer are.

It is actually not correct to say that ADI has existing operations as such in other MRI sites. As noted above, ADI currently does not provide MRI services. Some of ADI's radiologist owners have an indirect ownership interest in a separate company called Middle Tennessee Imaging, LLC d/b/a Premier Radiology. However, Premier Radiology is not the applicant for this CON. Nevertheless, in anticipation of the question posed in regard to Premier Radiology, we have completed the table below with respect to Middle Tennessee Imaging, LLC's (Premier's) locations:

Historical Utilization of Middle Tennessee Imaging, LLC MRI Locations

Provider	Current # units (type)	County	Distance from SSMI (miles)	2011	2012	2013	% Change '11-'13	# MRI procedures by Sumner County residents (2013)
Mobile MRI Medical Services	1 mobile	Montgomery	61.8	0	0	1,404	--	0
Premier Radiology Belle Meade	3 fixed	Davidson	37.2	7,408	7,355	6,582	-11.2%	450
Premier Radiology Brentwood	1 fixed	Davidson	38.2	774	854	1,189	53.6%	20
Premier Radiology Cool Springs	2 fixed	Williamson	47.6	3,828	3,645	3,095	-19.1%	17
Premier Radiology Hermitage	1 fixed	Davidson	28.3	4,869	4,897	4,536	-6.8%	467
Premier Radiology Midtown	2 fixed	Davidson	31.3	0	0	1,266	0.0%	73
Premier Radiology Mt. Juliet	1 fixed	Wilson	21.9	2,147	2,508	2,525	17.6%	131
Premier Radiology Murfreesboro	1 fixed	Rutherford	39.8	2,952	4,755	5,112	73.2%	9
Premier Radiology Nashville	1 fixed	Davidson	30.9	2,333	2,251	1,994	-14.5%	197
Premier Radiology Smyrna	1 fixed	Rutherford	38.4	1,585	2,484	2,370	49.5%	3
Premier Radiology St. Thomas Medical Plaza West	1 fixed	Davidson	37.7	0	0	0	0.0%	0
Total				25,896	28,749	30,073		1,367

January 23, 2015**12:41 pm****10. Section C, Economic Feasibility, Item 1**

The use of the estimated fair market values (FMV) for both the office space and the Extremity MRI scanner in the applicant's Project Costs Chart are noted. Thank you for providing the comparison with the actual estimated lease costs for these items.

With respect to the MRI cost, the applicant states that the \$500,000 FMV estimate for the MRI equipment cost is a generous estimate to obtain a new replacement scanner when it becomes necessary. Review of the vendor quote for the existing unit approved in Thomas Gautsch, MD, CN0110-88A and subsequently acquired in 2004 appears to indicate a cost of approximately \$534,990 with discount but before taxes and shipping. What developments in the manufacture of the General Electric E Scan X Q unit or comparable replacement unit since 2004 might account for acquisition at a lower total MRI new equipment/replacement cost at some future year?

Response: The referenced \$534,990 was for an optional \$120,000 service contract over the first four years, in addition to the quoted price of \$414,990 for the actual set-up, scanner, RF pavilion, control console, large format film printer, pads, wedges, coils, cabinet etc.; all shipped and installed. Based on our actual repair experience with this unit, and advice/experience of the technician with whom GE independently contracted to provide those services to us (at a greatly inflated price) we would not purchase a service contract with a replacement scanner. We'll do better to pay directly for the very few repairs typically necessary in those first years, expected to be less than \$50,000.

\$414,990 also included items that would not need to be re-purchased with replacement of the existing scanner: the approximately \$20,000 modular RF screened pavilion, and the \$30,000 Codonics 14" x 17" digital film printer, made obsolete by a PACS server, and the ability to securely access studies electronically or burn studies to cd.

Nevertheless, a generous estimate of \$500,000 to allow for a future replacement scanner was made to allow plenty of margin for price, tax, and even a replacement pavilion, operator console, computer, monitor, etc. and all still fit well within a \$624,935 estimated project cost for this application -- to continue the existing MRI services in Dr. Gautsch's office after he joins ADI.

11. Section C, Economic Feasibility, Item 2

Please provide documentation from the applicant's Chief Financial Officer that attests to the availability of sufficient cash reserves to support the project.

Response: Please see attached letter from the CFO of Advanced Diagnostic Imaging, P.C.

12. Section C, Economic Feasibility, Item 4

It would be helpful to have a Historical Data Chart for Advanced Diagnostics, PC that corresponds to the 2 most recent fiscal periods show in the financial statements provided with the application.

Response: Although an existing project, with existing services, this project is new to ADI which does not currently have any revenue from MRI services. Therefore, similar to other new projects, there is no historical ADI MRI data to report. ADI is a physician group with many employed physicians, all of whom are providing professional medical services. ADI does not conduct any technical services as a general matter. As noted, after joining ADI, Dr. Gautsch's use of the MRI machine will be the first instance where ADI will be providing MRI services. ADI's financials are provided to demonstrate ADI's financial standing as the applicant.

Historical Data Chart of SSMI-

Given the amounts shown for Gross Operating Revenue and Total Deductions, it appears that there are math errors in the calculation for Net Operating Revenue (NOR) in each of the 3 fiscal year periods shown in the table. For example, NOR in 2013 should be \$260,320 in lieu of the \$309,736 amount shown in the chart. As a result, net operating income of SSMI appears to be overstated. Please make the appropriate changes and submit a revised historical data chart in a replacement page for the application (page 25-R).

Response: Please see attached revised historical data chart, page 25-R.

As noted, the applicant states on page 28 that the cost for imaging interpretation services by radiologists is approximately \$100 per scan. As such, it appears the cost might be approximately \$72,300 in fiscal year 2013. Where are these costs reflected in the chart and what were the amounts by fiscal year period?

Absent any amounts in the chart for physician salaries, is it generally correct that Net Operating Income (NOI) can be interpreted to mean NOI before physician compensation? Please clarify.

What types of operating expenses account for Fees to Non-Affiliates in Line D.8.b. of the chart (average cost of approximately \$48,400 per year)?

Response: SSMI currently pays a group of outside Radiologists to provide readings of the studies. The cost of reading, secure file transfer and storage, expedited reads etc., is something a bit less than \$100 per study. This is reflected in the fees to non-affiliates listed in the Historical Data Chart, but is exclusive of those government funded programs which require the radiologists to bill for their services directly to the carrier.

Projected Data Chart -

Absent no appreciable increase in the number of MRI procedures performed between 2013 and Year 1, what accounts for the estimated 35% in gross operating revenues of the project?

Response: The increased charges are simply a result of Dr. Gautsch joining ADI. ADI has a set charge-master that it uses for all of its services. ADI does not alter its charge-master by location. Although billed charges/gross operating revenues will increase, they have been unusually low and will still be below average for Middle Tennessee, and far below average in Sumner County. Nevertheless, we believe that the billed charges will not be particularly relevant to patients or insurers, because the charges do not determine the amounts actually owed by patients or payors. Whether \$1,540 or \$2,107 is charged, Medicare will still only pay \$234.43. Similarly with other carriers, amounts owed are a function of the allowable for each insurance carrier, which is determined by CMS or the State, or as negotiated by contract in the case of commercial insurance carriers. In all cases the amounts owed for the services provided are significantly less than the billed charges. This is true for almost all medical providers. For uninsured patients, ADI has set self-pay rates that are significantly less than the billed charges.

In terms of projected Management Fees, it appears that the applicant expects to incur new costs related to "Fees to Affiliates" as a result of the merger with Advanced Diagnostic Imaging, P.C. and will no longer have expenses related to "Fees to Non-Affiliates". In addition, the management fees are expected to increase by approximately 154% from \$52,955 in fiscal year 2103 to \$134,505 in Year 1 of the project. Please explain.

Please identify the amounts budgeted in Operating Expenses pertaining to imaging interpretation fees by radiologists.

Response: Historically and currently at SSMI, commercially reimbursed studies are read by non-affiliated Radiologists, at a per study cost to SSMI, but they directly bill for government plans which require it. After approval, all studies will be billed "globally" to all payors and a portion for reading, the professional component, attributed to the "affiliated" ADI Radiologists reading them as an expense to this care center. Additionally, an additional 5% of net revenues management fee to cover centralized billing and collection costs will be accounted to this care center.

13. Section C, Economic Feasibility, Item 5

The applicant states that the average gross charge will be \$2,107 per MRI procedure. This amount is consistent with what is budgeted in the Projected Data Chart for the project. As such, this average gross charge equates to an increase of approximately 34% from the \$1,570 average gross charge reflected in the Historical Data Chart on page 25 of the application and the rate reflected in HSDA Equipment Registry records for 2013 (\$1,540 per procedure).

Given that there appears to be no major changes to the existing MRI service such as capital outlay for a new MRI scanner and no appreciable change in the payor mix as

January 23, 2015**12:41 pm**

reflected in the table on page 29, it is unclear how the project would have an impact of this magnitude on the charges of the existing MRI service. Please explain.

Response: The increased charges are simply a result of Dr. Gautsch joining ADI. For consistency, ADI has a set charge-master that it uses for all of its services. ADI's charge-master is used by all of its providers at all locations and type of service. Although important for accounting and internal consistency, in regards to economic feasibility, we believe that the change in billed charges will have little if any impact on patients or providers because billed charges do not determine the amounts actually owed by patients or payors. Net revenues are a function of the allowable rates for each insurance carrier, as determined by CMS (Medicare), TennCare, TriCare, VA, Work Comp boards, or as negotiated by contract, in the case of insurance carriers other than Medicare. In all cases the amounts received for services provided are both significantly less than the billed charges and unaffected by them. This is the case generally for almost all medical providers. For uninsured patients, ADI has set self-pay rates that are also significantly less than billed rates.

14. Section C, Economic Feasibility, Item 9

The table is noted. Please include an entry for Gross Operating Revenue by payor source in Year 1 of the project. Please provide the revised table below in a replacement page 29-R for the application.

Response: Please see attached revised table in a page 29-R.

Historical and Projected Service Payor Mix

Payor Source	2013 SSMI Gross Revenue (as a % of total)	Year 1 Applicant's Projected Gross Revenue	Year 1 Gross Revenue by Payor Source as a % of total
Medicare	17.7%	\$270,692	17.7%
TennCare	11.6%	\$177,403	11.6%
Managed care	10.3%	\$157,521	10.3%
Commercial	57.6%	\$880,896	57.6%
Self-Pay	0.5%	\$7,647	0.5%
Other	2.3%	\$35,175	2.3%
Total	100.0%	\$1,529,334	100.0%

15. Section C, Orderly Development, Item 3

The response is noted. Please complete the table illustrating the staffing planned by the applicant to continue staffing for the MRI service.

January 23, 2015**12:41 pm****Response:**

Position Title	Existing FTEs 2013	Projected FTEs Year 1	Average Wage	Area-wide Average Wage
RT with SSMI paid MR training	0.4	0.4	\$15.50	\$15-22**
RT/MR tech director	0.1	0.1	\$23.00	\$20-\$25**
Total	0.5	0.5	\$17.00	\$15-\$25

** Area-wide average wages are very rough estimates based on opinions and informal discussion. There are no other office based scanners in our primary or secondary service areas, with whom to compare, and we are unaware either of wages paid at other TN office based scanners, nor of data in their regard separate from the aggregation of all Hospital and ODC based staff in available labor statistical data.

January 23, 2015**12:41 pm****AFFIDAVIT**

STATE OF TENNESSEE

COUNTY OF DavidsonNAME OF FACILITY: Advanced Diagnostic Imaging, P.C.

I, Ryan Brown, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature] General Counsel
Signature/Title

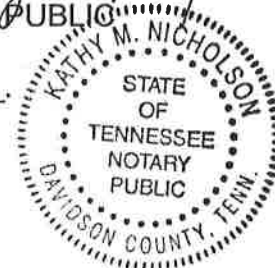
Sworn to and subscribed before me, a Notary Public, this the 23rd day of January, 2015
witness my hand at office in the County of Davidson, State of Tennessee.

Kathy M. Nicholson
NOTARY PUBLIC

My commission expires 3/8, 16.

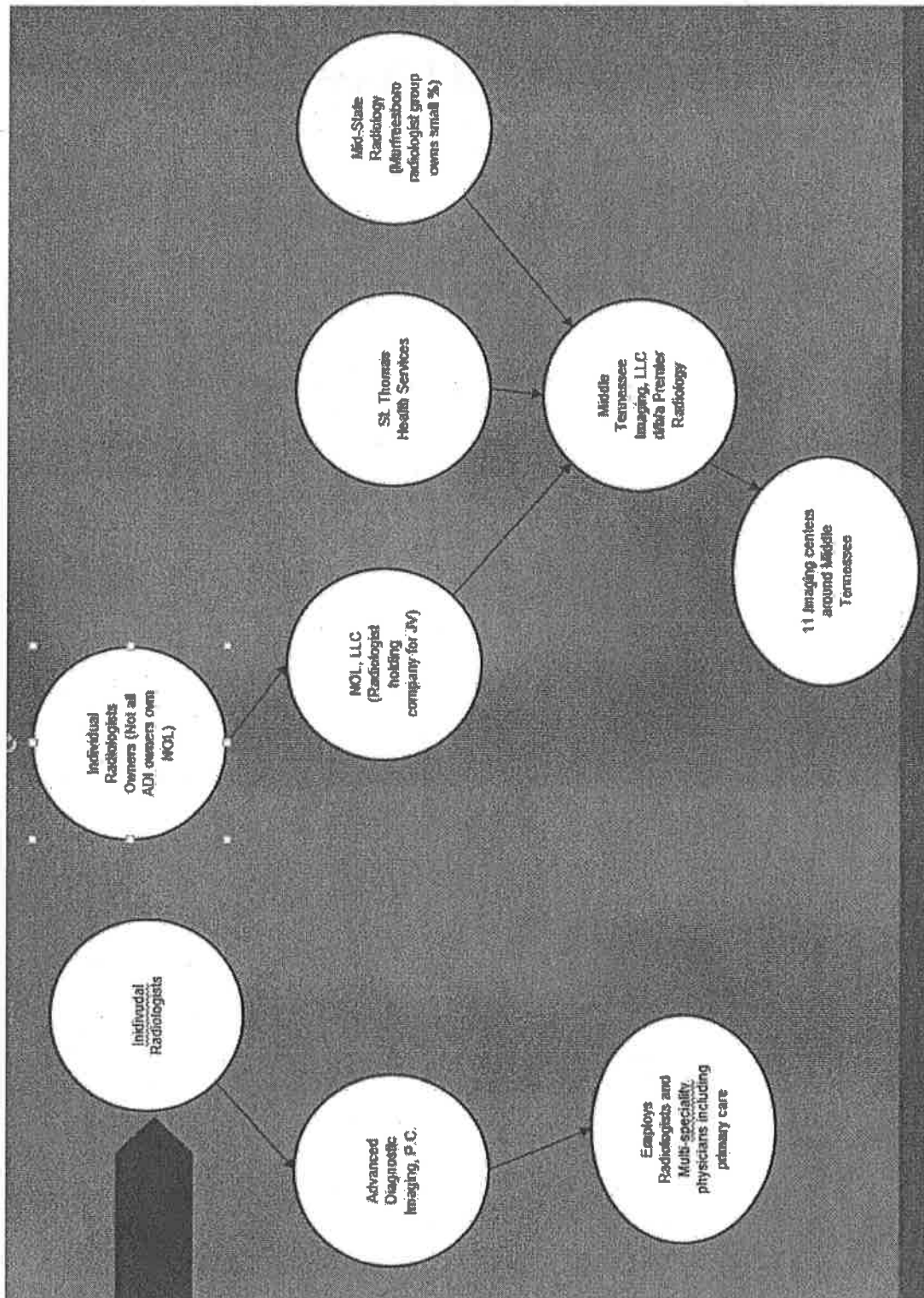
HF-0043

Revised 7/02



Attachments
Response to January 16
Supplemental Questions

Attachment
Section A, Item 3 Part 1
Organizational Charts for ADI and Premier Radiology



Attachment
Section A, Item 3 Part 2
List of all Premier sites that provide MRI services in TN

BELLE MEADE

28 White Bridge Pike Suite 111
Nashville, TN 37205

BRENTWOOD

789 Old Hickory Blvd.
Brentwood, TN 37027

COOL SPRINGS

3310 Aspen Grove Drive, Suite 101
Franklin, TN 37067

CLARKSVILLE

980 Professional Park Drive Suite E
Clarksville, TN 37040

HERMITAGE

5045 Old Hickory Blvd, Suite 100
Hermitage, TN 37076

MT JULIET

5002 Crossings Circle, Suite 140
Mount Juliet, TN 37122

MURFREESBORO

1840 Medical Center Pkwy SETON BUILDING | Suite 101
Murfreesboro, TN 37129

NASHVILLE (Charlotte Ave)

1800 Charlotte Avenue
Nashville, TN 37203

Saint Thomas MIDTOWN

300 20th Avenue North, Suite 202
Nashville, TN 37203

Saint Thomas WEST

4230 Harding Pike Suite 220
Nashville, TN 37205

SMYRNA

741 President Place, Suite 100
Smyrna, TN 37167

January 23, 2015**12:41 pm**

Attachment

Section A, Item 6

Tax Record

SUMNER COUNTY 2014 TAX NOTICE																																																														
<p style="text-align: center;">Marty Nelson, Trustee 355 Belvedere Drive N Room 107 Gallatin, TN 37066 • (615) 452-1260</p>																																																														
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Appraised value	\$591,300																																																													
Assessment	40 %																																																													
Assessed value	\$236,520																																																													
Tax rate	2.5000																																																													
Roll back	\$0.00																																																													
Current taxes	\$5,913.00																																																													
<p>Your cancelled check, along with your portion of this statement, serves as your receipt. If a receipt is required, please enclose a self-addressed stamped envelope.</p>																																																														
<p style="text-align: center;">Your payment options are:</p> <ul style="list-style-type: none"> • By mail: 355 Belvedere Drive N Room 107, Gallatin, TN 37066 <i>Payment postmarked after March 2, 2015 must include penalty.</i> • At our office, at that same address • Drive-thru window and payment drop box available, at that same address • At participating local banks * • On-line at our vendor's website: www.sumnertn.org * • Partial Payment Options * 																																																														
<p style="text-align: center;">*See back of notice for details</p>																																																														
<p style="text-align: center;">To pay your taxes, make checks payable to: Sumner County Trustee</p>																																																														
<p>To avoid penalty and interest, taxes must be paid by March 2, 2015.</p>																																																														
<p>Sumner County Trustee 355 Belvedere Drive N Room 107 Gallatin, TN 37066 Phone: (615) 452-1260</p>				<p style="text-align: center;">Office Hours: Monday thru Friday 8:00am - 4:30pm www.sumnertn.org</p>																																																										

**Attachment
Section C, Economic Feasibility, Item 2
CFO Statement**

January
12:41 p

ADVANCED

Diagnostic Imaging

January 20, 2015

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
500 Deaderick Street, Suite 850
Nashville, Tennessee 37243

RE: Advanced Diagnostic Imaging's request to allow the MRI services currently provided by Southern Sports Medicine Institute to be continued following Dr. Gautsch's employment by ADI.

Dear Ms. Hill:

Advanced Diagnostic Imaging, P.C. (d/b/a Advanced Health Partners d/b/a Southern Sports Medicine Institute) has sufficient resources available to fund all costs required for the development and establishment of the project as set forth in the certificate of need application. The funding needed for Administrative, Architectural, Engineering, Construction, and Equipment costs appears to be approximately \$625,000. Cash-on-hand will be used to fund this project.

If you need additional information, please contact me at 615-239-2039.

Sincerely,



Mark Gaw
CFO

John J. Albrecht, MD
Enrique R. Alvarez, MD
Matthew R. Bernhard, MD
Steven M. Blount, MD
Dana Bonanno, MD
Robert S. Burcham, MD
Chad L. Calandine, MD
Michael C. Chan, MD
Michael R. Cooper, MD
Kevin P. Cunniff, MD
Floyd D. Dunsavant, MD
Byard Edwards, III, MD
Tara M. Foster, MD
J. Michael Friday, MD
Jonathan R. Gordon, MD
Ariel A. Hogue, MD
Linda Harty, MD
Diet H. Hinzlborn, MD
Jeffrey M. Huppert, MD
Stephen P. Humphrey, MD
James C. King, MD
Michael J. Levitt, MD
Joe M. MacCuto, Jr., MD
David L. Magallon, MD
Michael S. Melnick, MD
Paul C. Neu, MD
Vraj K. Parikh, MD
Jose J. Puffis, MD
Melinda R. Sarr, MD
Steven T. Shino, MD
Vincent Standa, MD
Marc G. Suber, MD
Michael D. Spillner, Jr., MD
Gabriel L. Stamps, MD
Diet L. Thomsen, MD
David R. Watts, MD
Jeffrey T. Williams, MD
Daniel J. Wray, MD

COPY -Additional Info. SUPPLEMENTAL-1

**Southern Sports Medicine
CN1501-002**

January 27, 2015

Philip Grimm, MHA
HSDA Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th floor,
502 Deaderick St.
Nashville, TN 37243

RE: Certificate of Need Application CN1501-002
Advanced Diagnostic d/b/a Southern Sports Medicine Institute

Dear Mr. Grimm,
Following is the addendum response to your January 16 set of supplemental questions:

Additional Information - Supplemental 1

12. Section C, Economic Feasibility, Item 4

Projected Data Chart -

Please identify the amounts budgeted in Operating Expenses pertaining to imaging interpretation fees by radiologists.

Response: \$134,505 and \$135,246 in Years 1 and 2 respectively.

Historically and currently at SSMI, studies are read by non-affiliated Radiologists. For commercially reimbursed studies, reading is billed to SSMI at a per study cost. The Radiologists directly bill government plans that require it for the studies so covered. After approval, all studies will be billed "globally" by ADI to all payors. A fee for reading -- the professional component -- will be attributed to the "affiliated" ADI Radiologists reading them, accounted as an expense to this care center.

SUPPLEMENTAL

AFFIDAVIT

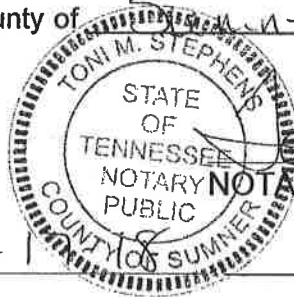
STATE OF TENNESSEE

COUNTY OF SumnerNAME OF FACILITY: ADI 2/5/9 Southern Spine Medicine
Institute

I, Thomas Gaunt, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature]
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 28th day of Jan, 2015,
witness my hand at office in the County of Sumner, State of Tennessee.



My commission expires 12-1-18

HF-0043

Revised 7/02



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

Date: March 4, 2015

To: HSDA Members

From: Melanie M. Hill, Executive Director

**Re: CONSENT CALENDAR JUSTIFICATION
CN1501-002 – Advanced Diagnostic Imaging d/b/a Southern Sports Medicine Institute**

As permitted by Statute and further explained by Agency Rule on the last page of this memo, I have placed this application on the consent calendar based upon my determination that the application appears to meet the established criteria for granting a certificate of need. If Agency Members determine that the criteria have been met, a member may move to approve the application by adopting the criteria set forth in this justification or develop another motion for approval that addresses each of the three criteria required for approval of a certificate of need. If you find one or more of the criteria have not been met, then a motion to deny is in order.

At the time the application entered the February 2015 review cycle, it was not opposed. If the application is opposed prior to being heard, it will move to the bottom of the regular March agenda and the applicant will make a full presentation.

Summary—

Advanced Diagnostic Imaging (ADI) d/b/a Southern Sports Medicine Institute (SSMI) is seeking approval to change the ownership of MRI equipment from Thomas L. Gautsch, P.C. d/b/a SSMI to Advanced Diagnostic Imaging d/b/a Advanced Health Partners due to the acquisition of Dr. Gautsch's medical practice by the larger ADI medical practice. More information regarding the acquisition can be found in the original application (pages 2, 5, 6).

Dr. Gautsch received approval under CN0110-088A to provide extremity MRI services as part of his orthopedic medical practice on January 23, 2002 by vote of 10-1. The service was implemented in 2004 and has been in continuous use since. In November 2014, Dr. Gautsch contacted agency staff regarding the pending acquisition and was advised since the CON was issued to his medical practice it could not be

transferred to ADI as part of the acquisition. Tennessee law permits the transfer of a certificate of need only if it is transferred as part of the transfer of ownership of a health care institution. Physician practices are not included in the definition of a health care institution. Therefore, in order for he and his medical partners to perform MRI procedures and be reimbursed using the same equipment at the existing site, this CON application was filed. This change of ownership simply reflects the changing health care landscape in which many physicians and institutions must now operate due to regulatory and reimbursement changes.

Executive Director Justification -

I recommend the Agency approve certificate of need application CN1501-002 based upon the following criteria:

Need-The need for the extremity MRI was established when the certificate of need was granted in January 2002. This approval simply changes the ownership of the equipment from a single physician practice to a large medical group, which will provide increased support services to this practice location. The change in ownership most likely will increase utilization since ADI is in network with more commercial and TennCare plans.

Economic Feasibility-The project is being funded by the cash reserves of the applicant. The only true cost of the project is the CON application filing fee and the legal fees associated with it.

Contribution to the Orderly Development of Health Care- The project does contribute to the orderly development of health care because these services will now be available to a broader scope of the population because ADI/AHP is in network with more commercial and TennCare plans than SSML was as a single practice. This increased network presence will help ensure access to this unique, specialty extremity MRI service.

Statutory Citation -TCA 68-11-1608. Review of applications -- Report

(d) The executive director may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

Rules of the Health Services and Development Agency - 0720-10-.05 CONSENT CALENDAR

- (1) Each monthly meeting's agenda will be available for both a consent calendar and a regular calendar.
- (2) In order to be placed on the consent calendar, the application must not be opposed by anyone

having legal standing to oppose the application, and the executive director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.

(3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with The Agency within thirty (30) days of the beginning of the applicable review cycle.

(4) If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by The Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of The Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.

(a) For purposes of this rule, the "next regular agenda" means the next regular calendar to be considered at the same monthly meeting.

(5) Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deadrick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

November 26, 2014

Thomas L. Gautsch, M.D.
652 Northridge Dr.
Gallatin, TN 37066

RE: Staff Determination Letter No. 2014-SDL-011
Thomas L. Gautsch, M.D., P.C. MRI

Dear Dr. Gautsch:

Certificate of Need (CON) #CN0110-088A was issued to Thomas L. Gautsch, M.D., P.C. in 2002. CN0110-088A is limited to the practice of Southern Sports Medicine Institute, PLLC and orthopedic extremity MRI.

It is my understanding that you are contemplating merging your practice into a larger multi-specialty entity which included radiologists. The MRI would remain for your patients but your practice would become a part of the larger umbrella entity and its tax ID for billing and contracting purposes.

You could request a modification of CN0110-088A's limitation to the practice of Southern Sports Medicine Institute, PLLC. Such a request would be considered by the HSDA at its monthly meeting following the month of your request. The limitation to orthopedic extremity MRI could not be modified, and would require a new CON if you wish to seek its elimination.

Since CN0110-088A was not issued to a *health care institution*,¹ the "larger umbrella entity" and its tax ID could not be used for billing and contracting purposes

¹ Health care institution means any agency, institution, facility or place that provides health services and that is one (1) of the following: nursing home; recuperation center; hospital; ambulatory surgical treatment center; birthing center; mental health hospital; mental retardation institutional habilitation facility; home care organization or any category of service provided by a home care organization; outpatient diagnostic center; rehabilitation facility; residential hospice; or non-residential methadone treatment facility. Health care institution does not include any premises occupied exclusively as the professional practice office of a physician licensed pursuant to the provisions of title 63, chapter 6, part 2 and title 63, chapter 9, or dentist licensed by the state and controlled by such physician or dentist. See T.C.A. §68-11-1602.

regarding the MRI issued to Thomas L. Gautsch, M.D., P.C. Tennessee law provides that:

"Except as provided in this section, the transfer of a certificate of need shall render it and all rights thereunder null and void. As used in this section, "transfer" means:

(1) Any sale, assignment, lease, conveyance, purchase, grant, donation, gift or any other direct or indirect transfer of any nature whatsoever of a certificate of need; provided, that nothing herein shall prohibit the transfer of a certificate of need. . . if the certificate of need is transferred as part of the transfer of ownership of an existing health care institution. . ."

T.C.A. § 68-11-1620(a). Therefore, the "larger umbrella entity" you referenced would be required to have its own CON for MRI services to perform or bill for MRI services.

You stated that the MRI would not move. Please be advised that, if you decide to move it in the future, a CON would be required to relocate the MRI service.

This determination is based upon the facts as presented. Should these facts change, this determination would also be subject to change.

Sincerely,



James B. Christoffersen
General Counsel

cc: Ann Reed, Director of Licensure, Health Care Facilities, Department of Health

MRI CON changes

Thomas Gautsch [tlgautsch@me.com]

Sent: Tuesday, October 28, 2014 1:21 PM

To: Jim Christoffersen

Attachments: MRI CON.pdf (60 KB) ; HSDA meeting february2004 ~1.pdf (1016 KB)

*** This is an EXTERNAL email. Please exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email - OIR-Security. ***

Hi Mr. Christofferson,

Many years ago I obtained an MRI CON (which I've attached) with limitations to be for the patients of my practice and the scanner we purchased. It was below a threshold dollar amount and actually reissued by the time I implemented it to allow a different (newer) magnet than specified originally and also at a different address to which I had moved my office.

Now I am contemplating merging my practice into a larger multi specialty entity which included radiologists. The MRI would not move and would remain for my patients but my practice would become a part of the larger umbrella entity and its tax ID for billing and contracting purposes. The actual MRI services would still be those currently provided on this magnet at this location for my patients. Do I need to do anything in regards the CON to continue to provide my patients with those MRI services but bill under the bigger entity?

Thanks,

Tom Gautsch

STATE OF TENNESSEE
HEALTH FACILITIES COMMISSION

Certificate of Need CN0110-088A is hereby granted under the provisions of
T.C.A. §68-11-101, *et seq.*, and the rules and regulations issued thereunder by this Commission

to Thomas L. Gautsch, M.D., P.C.
652 Northridge Drive
Gallatin, TN 37066

for Thomas L. Gautsch, M.D., P.C.

This Certificate is issued for the initiation of in-office magnetic resonance imaging (MRI) services utilizing a GE Lunar E-scan 0.2 Tessa open dedicated MRI for extremity scanning in the office of and in conjunction with the practice of Southern Sports Medicine Institute, PLLC. The MRI scanner and support space will occupy 324 of 4200 square feet of leased space. The MRI authorized by this Certificate of Need is limited to a unit the functionality of which is exclusively for imaging of the upper extremities from the shoulder to the fingers and the lower extremities from the hips to the toes.

CONDITION: Limited to orthopedic extremity MRI.

on the premises located at 608 Commons Drive
Gallatin (Sumner County), TN 37066

for an estimated project cost of \$693,000.00

The Expiration Date for this Certificate of Need is

(March 1, 2004)

or upon completion of the action for which the Certificate of Need was granted, whichever occurs first. After the expiration date, this Certificate of Need is null and void.

Date Approved January 23, 2002

Date Issued February 27, 2002


Chairman


Secretary

MAY. 3. 2004 3:03PM

TRAUGER_NEY_&_TUKE

NO. 9283 P. 4

STATE OF TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY



Certificate of Need No. CN0110-088A is hereby granted under the provisions of T.C.A. §68-11-1601, *et seq.*, and rules and regulations issued thereunder by this Agency.

To: Thomas L. Gautsch, M.D., P.C.
652 Northridge Drive
Gallatin, TN 37066

For: Thomas L. Gautsch, M.D., P.C.

This Certificate is issued for: the initiation of in-office magnetic resonance imaging (MRI) services utilizing a GE Lunar E-scan 0.2 Tessa open dedicated MRI for extremity scanning in the office of and in conjunction with the practice of Southern Sports Medicine Institute, PLLC. The MRI scanner and support space will occupy 324 of 4200 square feet of leased space. The MRI authorized by this Certificate of Need is limited to a unit the functionality of which is exclusively for imaging of the upper extremities from the shoulder to the fingers and the lower extremities from the hips to the toes.

CONDITION: Limited to orthopedic extremity MRI.

* This Certificate is a replacement of the originally issued Certificate of Need pursuant to Agency Rule 0720-3-06(g). Modification and/or addendums to issued certificates. In the event a certificate holder wishes to make substantive changes relating to the scope, cost, or duration of the project, written request must be made to, and formally approved by the Agency. If approved, such changes may be reflected in either the issuance of a modified Certificate of Need, or the issuance of an addendum to the original Certificate of Need. The Certificate of Need was originally approved at the January 23, 2002 meeting with a March 1, 2004 expiration date.

On the premises located at: 608 Commons Drive
Gallatin (Sumner County), TN 37066

For an estimated project cost of: \$693,000.00

The Expiration Date for this Certificate of Need is
September 1, 2004
~~March 1, 2004~~


or upon completion of the action for which the Certificate of Need was granted, whichever occurs first.
After the expiration date, this Certificate of Need is null and void.


Date Approved: January 23, 2002

Date Issued: February 27, 2002

* Modification Approval Date: March 24, 2004

HP-0022 (Rev. 1/04)


Chairman


Secretary

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT**

DATE: March 31, 2015

APPLICANT: Advanced Diagnostic Imaging, P. C.
d/b/a Southern Sports Medicine Institute
570 Hartsville Pike
Gallatin, Tennessee 37066

CN1501--002

CONTACT PERSON: Byron R. Trauger, Esquire
222 Fourth Avenue North
Nashville, Tennessee 37219
615-741-1954

COST: \$624,935

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

Advanced Diagnostic Imaging, P.C., a professional private practice owned by itself, with an ownership type Professional Corporation, and managed by itself, seeks Certificate of Need a(CON) approval allowing existing MRI services granted to Thomas L. Gautsh M.D., P.C. in the office of in conjunction with the practice of Sothern Sports Medicine Institute to continue to be provided in the same location, ADI, d/b/a Advanced Health Partners, a multi-specialty physician group private practice that Dr. Gautsh is joining. No new equipment or construction will be required. The same open, extremity scanner and location, 570 Hartsville Pike, Gallatin, Tennessee, will be used and remain in place. The total anticipated cost of the project is \$625,935, inclusive of the value of the occupied space, legal/consulting fees associated with the application, and potential future cost of the replacement of the existing MRI unit. The total cost will be \$624,935 and will be funded through cash reserves as documented in Supplemental 1, Economic Feasibility, Item 2.

This application has been placed on the Consent Calendar. Tenn. Code Ann. § 68-11-1608 Section (d) states the executive director of Health Services and Development Agency may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's projected service area is Sumner County. The population projections for Sumner County are 175,054 in 2015 increasing to 186,146 in 2019, an increase of 6.3%.

The service area utilization according to the HSDA equipment registry is provided in the chart below.

HSDA Service Area 2013 MRI Equipment Utilization

Facility	County	Fixed	Procedures	Mobile	Procedures
Diagnostic Center at Sumner Station	Sumner	1	1,948	0	0
Outpatient Imaging at Hendersonville Med. Center	Sumner	1	1,670	0	0
Portland Diagnostic Center	Sumner			1	289
Southern Sports Medicine Institute	Sumner	1	2,578	0	0
Sumner Regional Medical Center	Sumner	1	3,064	0	0
TriStar Hendersonville Medical Center	Sumner	1	2,565	0	0
Total		5	11,825	1	289

Source: HSDA 2013 Equipment Utilization

The total procedure for the 5 full-time units was 11,825 or 2,365 per fixed unit. If the 289 procedures from the one mobile unit are added, the result is 2,019 procedures per unit.

In 2001, CN0110-088A was granted to Thomas L. Gautsch, M.D., PC in the office of and in conjunction with the practice of Southern Sports Medicine Institute (SSMI), limited to orthopedic extremity MRI to obtain the first office based open scanner of its kind in Middle Tennessee.

SSMI is formally joining with other physicians as part of the multispecialty physician group Advanced Health Partners. The applicant will do business as Southern Sports Medicine Institute and the practice will not change significantly. However, joining SSMI with Advanced Health Partners and its larger range of contracts will allow a broader patient base from the service area to be seen at SSMI within their insurer's network. This partnership will involve patients in new exchange plans, additional commercial plans, and additional TennCare MCOs contracted with Advanced Health Partners/Advanced Diagnostic Imaging to be able to access SSMI within their network.

When the initial CON was granted there were two physicians in the SSMI practice, including Dr. Gautsch. Since that time, 8 additional physician and non-physician providers have worked with the group. Currently Dr. Gautsch and one AHP physician provider and one non-physician provider who are expected to order extremity MRI with the scanner. There are plans to replace one addition provider who recently left. Currently there are no other AHP/ADI physician practices in Sumner County.

TENNCARE/MEDICARE ACCESS:

The applicant participated in both the Medicare and TennCare programs. The applicant contracts with United Healthcare Community Plan, AmeriGroup, TennCare Select, and BlueCare.

The applicant projects \$270,692 in Medicare revenues, or 17.7 of gross revenues, and TennCare revenues of \$177,403, or 11.6% of gross revenues in year one of the project.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and if the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Revised Project Costs Chart is located on page 22 of the application. The total estimated project cost is \$624,935.

Historical Data Chart: There is no Historical Data Chart on page 25R of Supplemental 1. The applicant reported 636, 720, and 723 scans in 2011, 2012, and 2013 with net operation income of \$170,371, \$221,059, and \$198,538 each year, respectively.

Projected Data Chart: The Projected Data Chart can be found on page 26 of the application. The applicant projects 726 and 730 scans in years one and two with net operating income of \$228,575 and \$229,918 each year, respectively.

The applicant projects an average charge of \$2,087 for CPT code 73221 and \$2,126 for CPT code 73726. Their average charge per scan is projected to be \$2,107 per extremity scan.

The only option to this project would be to bring the practice into ADI and discontinue the existing MRI service. This was not considered a viable option.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The applicant provides a listing of all contracts and agreements they have for health services on page 30 of the application.

The applicant believes there will be no negative impact as a result of the project as no new MRI will be added to the service area.

There will be no new staff as a result of this project.

This office based MRI does not require licensure by the Tennessee Department of Health.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

**Magnetic Resonance Imaging
Standards and Criteria**

1. Utilization Standards for non-Specialty MRI Units.

- a. An applicant proposing a new non-Specialty stationary MRI unit should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2800 procedures per year by the third year of service and for every year thereafter.

This Criterion does not apply. This is an existing Specialty MRI.

- b. Providers proposing a new non-Specialty mobile MRI unit should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

This Criterion does not apply. This is an existing Specialty MRI.

- c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

This Criterion does not apply. This is an existing Specialty MRI.

- d. Mobile MRI units shall not be subject to the need standard in paragraph 1b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's geographical area are not adequate and/or that there are special circumstances that require these additional services.

This Criterion does not apply. This is an existing Specialty MRI.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

This Criterion does not apply. This is an existing Specialty MR and is accessible to 75% of the service area.

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

This Criterion does not apply. This is an existing Specialty MRI.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: $1.20 \text{ procedures per hour} \times \text{twelve hours per day} \times 6 \text{ days per week} \times 50 \text{ weeks per year} = 3,600 \text{ procedures per year}$

Mobile MRI Units: $\text{Twelve (12) procedures per day} \times \text{days per week in operation} \times 50 \text{ weeks per year}$. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

This Criterion does not apply. This is an existing fixed Specialty MRI.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:
1. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
 2. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit is in compliance with the federal Mammography Quality Standards Act;
 3. It is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

This Criterion does not apply. This is an existing Specialty MRI.

- b. Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity.

This is an existing Specialty MRI unit typically available for a total of 17 hours per week, divided into two and a half days per week. It operates 50 weeks per year, for a total of 850 operating hours per year. At 720 scans per year, the scanner is performing at 85%.

- c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall

then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity.

This is an existing fixed Specialty MRI.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.

This Criterion is not applicable. This is an existing extremity MRI.

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

The scanner is FDA approved.

- b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The existing scanner is installed in a physical environment that conforms to all applicable standards.

- c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.

The MRI is already an integral part of this physician medical office and practice. After the merge with ADI, emergencies will still be managed by the physicians and certified medical staff in conformity with accepted medical practices and transport will be by paramedics across the street of the Emergency Department of the hospital.

- d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.

All MRIs have been previously and will continue to be physician ordered and medically necessary.

- e. An applicant proposing to acquire any MRI Unit, including Dedicated Breast and Extremity MRI Units, shall demonstrate that:

- f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

All standards and protocols are currently in place, are according to Board-certified radiologist's instruction and supervision, and meet the standards necessary to obtain its current ICAMRL certification. All scans are and will be interpreted by a board certified radiologist.

- g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

The MRI is already an integral part of this physician medical office and practice. After the merge with ADI, emergencies will still be managed by the physicians and certified medical staff in conformity with accepted medical practices and transport will be by paramedics across the street of the Emergency Department of the hospital. Dr. Gautsch has admitting privileges at both Sumner County hospitals.

8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant agrees to supply all required data as described.

9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

This criterion is not applicable.

- b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

This criterion is not applicable.

- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

This partnership will involve patients in new exchange plans, additional commercial plans, and additional TennCare MCOs contracted with Advanced Health Partners/Advanced Diagnostic Imaging to be able to access SSMI within their network.

